Participant Information Sheet/Consent Form

Title	BIO|CONCEPT.BIOMONITOR III
Short Title	BM3CONCEPT
Protocol Number	RD020
Project Sponsor	BIOTRONIK Australia
Principal Investigator	*[Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]* **<Associate Inv's details if required by institution – delete if not required>**
Location	*[Location]*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this study. This is because your doctor is concerned that you may have an abnormal heartbeat, known as a "cardiac arrhythmia". Abnormal cardiac arrhythmias include inappropriate slow, fast or irregular heartbeats. This study is testing a new Insertable Cardiac Monitor (ICM) that is able to remotely monitor and record your heart rhythm over a long period of time for the detection and diagnosis of abnormal arrhythmias. The device itself does not deliver any therapy. The new ICM device is called BIOMONITOR III.

This Participant Information Sheet and Informed Consent Form tells you about the study. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

This study has been reviewed and approved by a Human Research Ethics Committee and will be conducted according to the *National Statement in Ethical Conduct in Human Research (2007).* This statement has been developed to protect the interests of people who agree to participate in human research activities.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will only be included in case you provide your consent to participation and to the processing of personal data in written form. You will receive the best possible care whether or not you take part.

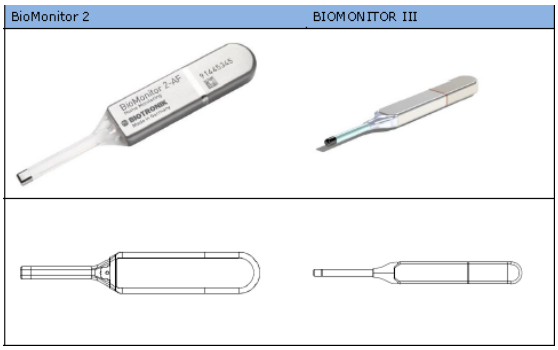
If you decide you want to take part in the study, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read.
- Consent to take part in the study.
- Consent to have the tests and treatments that are described.
- Consent to the use of personal and health information as described.

You will be given a copy on this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The primary aim of this study is to confirm the safety and efficacy of the BIOMONITOR III system. In addition, the insertion procedure, the use and handling of the special procedural tools and the sensing quality of the BIOMONITOR III will be assessed. The BIOMONITOR III is an experimental device. This means that it is **not** an approved device for the detection and diagnosis of abnormal arrhythmias in Australia.



BIOMONITOR III is a third generation ICM and is significantly smaller than the predecessor, the BioMonitor 2, which is already approved for the diagnosis of arrhythmias in Australia. The insertion procedure and respective tools have been optimised to improve the patient´s comfort and the usability of the device.

BIOMONITOR III is able to detect slow, fast or irregular heartbeats and can record them in a heart tracing (Electrocardiogram or ECG). The BIOMONITOR III records those activities automatically, but you are also able to record and save such activities yourself when you experience symptoms, by using a small device called the Remote Assistant III. This is a hand-held, battery-operated, radio-frequency device used to trigger a recording of the BIOMONITOR III.

At the follow-up visits, your study doctor is able to read the recorded data and determine if and what kind of arrhythmias occurred, such as rapid and irregular beating of the atria, known as atrial fibrillation. Your doctor can also read the recorded data via the Home Monitoring Service Centre (HMSC), a protected internet platform from BIOTRONIK.

Up to 45 eligible patients will be included in this study in up to 15 clinical sites located in Australia.

This research is being sponsored and conducted by BIOTRONIK Australia Pty. Ltd., Pymble, Australia.

3 What does participation in this research involve?

Your participation in this study will involve the following visits and procedures:

- Study enrolment.
- Insertion of the device.
- 1-week follow-up.
- 1-month telephone follow-up.

During participation in BIO|CONCEPT.BIOMONITOR III, we recommend not to participate in another study, unless the other study is a non-interventional study (meaning there are no procedures outside of routine clinical care). If at any stage you want to participate in another interventional study, please tell your doctor. In such cases, it may not be possible for you to continue in BIO|CONCEPT.BIOMONITOR III.

Enrolment procedure

Prior to participation you will be informed about the research in oral and written form and will be asked to provide written consent before any information is collected for research purposes. Your doctor will answer all questions you might have and will give you ample time to decide if you want to participate in the research.

At the enrolment visit, your medical history will be checked to ensure that the study is suitable for you. Your study doctor will provide you with a patient identification card which contains information about your study participation and the advice that your study doctor has to be contacted in case of a medical event. Please keep this identification card with you during the complete course of your study participation and present it to each doctor you visit.

If you are female and of child bearing age a pregnancy test may be required.

Data collection

After you have provided consent, your treating doctor will document basic personal information such as age and sex, health information, information on unwanted/unintended medical occurrences (side effects and other adverse events). This information will be entered in a research database and will be available to BIOTRONIK. All information entered in the database will use an anonymous participant ID code. BIOTRONIK will not have access to your name or identifying details. Only data required for the purpose of this study will be collected. Please ask your doctor in case you are interested in further details on the collected data.

What happens with my data?

Within this clinical investigation personal information, including medical data (personal data concerning health), will be collected from you. Your physician will document all information needed for your treatment in your personal hospital patient record. Your patient hospital record is accessible only to hospital personnel and BIOTRONIK representatives who are bound to confidentiality. Additionally, authorised designees of competent authorities or ethics committees, who are also bound to confidentiality, may access your personal patient record at your hospital in order to supervise the proper conduct of the clinical study.

Data collected for this clinical investigation will additionally be pseudonymised for transmission to the sponsor, who will store and analyse the pseudonymised data. “Pseudonymised” means that the data does not contain your name but an artificial identifier made of letters and numbers instead. With this code and a patient list kept in your hospital, the pseudonymised data set can be reconnected to your identity by authorised persons if required. Only pseudonymised data will be analysed by BIOTRONIK for the purpose of the study.

In addition to the data provided by your treating doctor, the sponsor also uses for the purposes of this study the data of your device transmitted via the BIOTRONIK Home Monitoring system and ReportShare function in a pseudonymised form.

Data is secured against unauthorised access. Decoding will be performed according to legal terms and conditions as outlined in the European data protection laws. Data analysis may be performed by BIOTRONIK, its affiliated companies or third parties as designated by BIOTRONIK.

Please note the additional details on data protection in the special section headed “Specific data protection according to European regulations for data transferred to and processed in the European Union” in Part 2, section 14.

Your individual participation in this study will be handled confidentially.

What happens with my data in case I withdraw my consent?

In case you chose to withdraw your consent both concerning study participation as well as concerning the processing of personal data, you will no longer be able to take part in the study and no further data collection for the study, neither via the BIOTRONIK Home Monitoring and ReportShare nor by the study team, will occur.

You also have the option to only withdraw your consent for study participation, leaving the consent for the processing of personal data unaffected. This would allow BIOTRONIK to further store, process and analyse the pseudonymised data that was collected prior to your withdrawal. Otherwise, that data will be anonymised or deleted so that it is impossible to reconnect the data to your identity.

Insertion

At the insertion visit, a BIOMONITOR III will be inserted by simple surgery directly under your skin on your chest. The insertion of the BIOMONITOR III device is performed in a sterile environment such as a Cardiac Catheterisation Laboratory or an Operating Theatre. You may receive a sedative through a small needle in your arm prior to the procedure to keep you comfortable. In most cases, the device will be inserted in the left chest area. Your doctor will determine the most appropriate insertion site for you. The area will be numbed with local anaesthetic before a small cut is made in the skin. The BIOMONITOR III device is inserted under the skin using a special tool that is provided with the device.

The implantation procedure is a day only procedure. As a key focus of this study is the insertion procedure, the investigator has to carefully assess the insertion procedure and the handling of the system components. Additionally, you will be asked if you consent to the insertion of BIOMONITOR III being recorded by a video camera. Your face will not be identifiable in that recording. The video recording is optional.

Before you are discharged from the hospital you will be given a Remote Assistant III. This is a small device that is used to activate the recording of an episode of your current arrhythmia and to store a heart tracing, known as an electrocardiograms or ECG, in the BIOMONITOR III device. You will be asked to activate the Remote Assistant III in case of light-headedness or when you feel unwell. The Remote Assistant III will be tested before you leave the hospital and a sample ECG will be recorded.

BIOMONITOR III is equipped with the BIOTRONIK Home Monitoring function which will be activated at this visit. With this function, your device regularly transmits medical and technical data (information) from your implanted device to an external device (CardioMessenger). You will receive the CardioMessenger from your study doctor and taught how to use it.

The CardioMessenger transmits (sends) data via a mobile network to BIOTRONIK. By consenting to study participation, you allow BIOTRONIK to transmit, receive and analyse your data. The data will be processed and provided to your study doctor.

Please note that your study doctor is only able to observe Home Monitoring data during office hours. Therefore, **Home Monitoring is not an emergency system. In the event of an emergency or disturbances, you should immediately seek medical care.** Data transmitted via Home Monitoring can only support your diagnosis and therapy; it cannot replace in-hospital follow-ups with your study doctor.

For documentation of medical symptoms, you have the option to download the BIOTRONIK Patient APP for use with a private smartphone. The Patient APP software provides a symptom diary in which you may describe the exact time of occurrence, nature and duration of medical symptoms. However, using the patient APP is completely voluntary, since you are also free to report any symptoms to your study doctor in any other way. Not using the Patient APP will not leave you at any disadvantage.

Data of the symptom diary will be transmitted via cellular networks to BIOTRONIK and will be made available to the investigator via the BIOTRONIK Home Monitoring Service (see above). However, the Patient APP software is **no emergency system**. In the event of an emergency or disturbances, you should immediately seek medical care.

1-week follow-up visit

If you participate in this study, you will be asked to return for 1-week follow-up visit. The follow-up examination will take about 5-10 minutes longer than a standard follow-up in order to investigate the functionality of the device in more detail.

At the follow-up visits, your study doctor will examine your BIOMONITOR III and may optimise or adjust the settings specifically to your needs. Additionally, your study doctor will check your wound to ensure it is healing and will ask you about any medical events that may have occurred since the insertion procedure.

1-month telephone follow-up

1-month after the insertion procedure, your study doctor will contact you via a telephone call so that they can inform you about the proper function of your BIOMONITOR III from the data sent to them via Home Monitoring. The study doctor may also ask you some questions, such as questions about any medical events that might have occurred since your last visit.

Study Termination

Your study participation will end after the 1-month telephone follow-up with your study doctor. Your study doctor will discuss your ongoing medical management with you and will let you know when he would like to see you again. Your doctor will continue to receive information from the BIOMONITOR III until he decides the device is no longer necessary. At that time, the device will be removed during a simple surgical procedure.

A premature study termination may occur, for example if you are excluded from further study participation for any reason or in case you withdraw your consent. If you terminate from the study prematurely, it is the study doctor's decision how to proceed with your long-term cardiac rhythm monitoring. Your doctor may continue to gather information with the device as per standard of care or he may deem it as no longer necessary and remove the device.

In case of medical events which are related to the investigational devices and are unresolved at study termination, your study doctor will forward information concerning these events to the BIOTRONIK at the time of your study termination and also after official study termination for the study for up to 4 weeks or until the event's resolution, whichever comes first.

Additional Costs

There are no additional costs associated with participating in this research study, nor will you be paid. However, travel expenses can be reimbursed up to $70 upon presentation of the receipts for the additional study-related 1-week in-hospital visit.

Travel expenses for regular visits according to clinical routine will not be reimbursed when they coincide with regular study-related visit to the hospital. Please contact the study staff for further information on reimbursable travel costs.

You may have to give your bank account details to the doctor or any other responsible party in the clinic for the compensation to be transferred to your account. Depending on the institution's policies cash may be reimbursed to you. If this is required you need to discuss this with the study staff.

4 What do I have to do?

The insertion procedure with the BIOMONITOR III does not differ from the standard ICM insertion procedures that would be done if you were not in this study. The procedure will be completed in line with the standard of care at [Institution]. However, the study uses a new incision and insertion tool that are part of the BIOMONITOR III system.

It is very important that you understand the requirement of your return for the follow-up visit and the participation in the telephone follow-up. This is to assess the device performance and to optimise and adjust all settings specifically to your needs.

If you decide to participate in this study, with your consent the study doctor may inform your local doctor.

5 Do I have to take part in this study?

Participation in any study is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with *[Institution]*.

6 What are the alternatives to participation?

You do not have to participate in this study to receive treatment or a diagnosis at this hospital. Due to your heart arrhythmias, your doctor decided an ICM should be inserted regardless of your study participation. Other options are available if you do not participate. This may include other ICMs that are already approved in Australia. Your study doctor will discuss these options with you before you decide whether or not to take part in this study. You can also discuss the options with your local doctor.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include the receipt of the newest implantable cardiac monitor of the BioMonitor family, which is manufactured according to the latest technology.

By participating in this study, you agree to the detailed analysis of the BIMONITOR III insertion procedure and functionality which includes the more detailed follow-up examinations compared to normal follow-up visit. This means you will get a broader medical examination than other patients as described above.

8 What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs your study doctor may need to stop your treatment or the procedure. Your study doctor will discuss the best way of managing side effects with you.

The BIOMONITOR III has a lot of similarities to other ICMs, which are used to monitor abnormal heart beats. A BIOMONITOR III insertion procedure does not differ from the other similar ICM insertion procedures and therefore, involves no greater risk. The below risks apply to routine insertion procedures and are not limited to the study. Possible complications include, but are not limited to:

- Bruises around the wound.
- Extrusion (force out) from the insertion.
- Fluid accumulation (build-up).
- Infection at the insertion site.
- Pain at the insertion site.
- Healing problems post insertion.
- Rejection (including local tissue reaction) of the device.
- Migration of the device (movement from the normal position).
- Erosion through the skin.
- Protrusion of the device (a bulge above the surface).

The follow-up examinations for BIOMONITOR III are the same as routine follow-ups with other available ICMs. Thus, there are no additional burdens or risks for you by participating in this study.

However, the analysis at the implantation and during the follow-up visits are conducted and documented in a more detailed manner which may lengthen the time of your visit when compared to a standard clinical follow-up visit.

It is important that study participants are not pregnant or breast-feeding and do not become pregnant during the course of the study. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you do become pregnant whilst participating in the study, you should advise your study doctor immediately.

9 What if new information arises during this study?

Sometimes during the course of a study, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information, our study doctor might consider it to be in your best interested to withdraw you from the study. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

10 Can I have other treatments during this study?

Whilst you are participating in this study, it is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the study.

11 What if I withdraw from this study?

You are free to withdraw from the clinical investigation at any time without giving any reason. You will not be at a disadvantage if you withdraw from the study, nor are there any direct consequences. You will continue to receive usual care as appropriate for your medical condition.

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the study results.

If you decide to withdraw, you may be asked to complete a 'Form of Withdrawal of Participation' but you do not have to fill in this form in order to withdraw from the study. In case you chose to withdraw your consent during the study, no further data collection for the study, via Home Monitoring nor by the study team, will occur. BIOTRONIK will not store, and analyse the pseudonymised data that was collected prior to your withdrawal unless otherwise allowed by you.

12 Could this study be stopped unexpectedly?

This study may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects.
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.
- Further participation in the clinical study is medically intolerable according to the opinion of your doctor.
- Your further participation in the clinical study is no longer justifiable due to non-compliance to the study instructions (e.g. non-adherence to the mandatory time window between providing consent and having your follow-up visit).
- Premature termination of the whole clinical investigation due to e.g. new information indicating non-tolerable risks for the patients.

13 What happens when the study ends?

When the study ends you will continue care with your usual doctor and can request to be provided with a summary of the results when the study is fully completed and the results are analysed. Your treating doctor will provide you with information about this.

Part 2 How is the study being conducted?

14 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the study. Any information obtained in connection with this study that can identify you will remain confidential. All information will be kept in the locked Cardiology research office and is accessible only to hospital personnel and BIOTRONIK representatives who are bound to confidentiality. Your information will only be used for the purpose of this study and it will only be disclosed with your permission, except as required by law.

Information about your participation in this study may be recorded in your health records. Your health records and any information obtained during the study are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised

representatives of the Sponsor, BIOTRONIK Australia Ltd or its representative, the institution relevant to this Participant Information Sheet, *[insert name of Institution]*, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this study.

The collection and analysis of your medical data will be done in accordance to the European data protection law (Directive 95/46/EC) and with relevant Australian privacy legislation and other relevant laws and regulations.

Data from your medical record connected to your treatment will be entered into an electronic database. It is important for you to understand that any data entered into the database will be de-identified and your confidentiality will never be compromised in any way or form. Your name and address will not be available to anyone outside the hospital. In addition to the data provided by your treating doctor, the data transmitted via the Home Monitoring system is used by the sponsor in a de-identified format.

Your de-identified data and images may be sent to other countries, including the United States of America, by BIOTRONIK for analysis and storage. Data will be sent to Germany and USA for analysis. Only de-identified data will be sent (data without your name and date of birth). Data will be subject to European data laws (see below) in Europe, and will be protected by contracts that require the same level of protection in the USA. The Data Protection Statement below outlines this in more detail.

SPECIFIC DATA PROTECTION ACCORDING TO EUROPEAN REGULATIONS FOR DATA TRANSFERRED TO AND PROCESSED IN THE EUROPEAN UNION

Study data collected in this study will be transferred to BIOTRONIK`s parent company located in the European Union (EU). Your data which will have a unique identification number and will be accessed, processed and distributed to 3rd parties (e.g. Competent Authorities in the EU) as required. Your data is protected within the EU according to the General Data Protection Regulation (GDPR). The following regulations apply for your data in the EU:

- Data is secured against unauthorised access.
- Data privacy and security measures have been implemented by BIOTRONIK to ensure appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage. BIOTRONIK adheres to applicable European data protection laws at all times.

In case you withdraw your consent, you will no longer be able to take part in the study and no further data collection for the study will occur. You have the option to only withdraw your consent for study participation, leaving the consent for the processing of personal data unaffected. This would allow BIOTRONIK to further store, process and analyse the data that was collected prior to your withdrawal. Otherwise, that data will be anonymised or deleted so that it is impossible to reconnect the data to your identity.

Data Protection Statement:
By signing the consent form, you agree that you have been informed that personal data will be processed in terms of this clinical investigation. The data will only be processed in accordance with the applicable statutory regulations. This presupposes a voluntarily given consent. Study participation is only possible after you have given written consent to data processing. You are being provided with the following information about data protection:
1. Controller A controller is a responsible entity for the processing of personal data. For this study these are: • BIOTRONIK SE & Co. KG, Woermannkehre 1, 12359 Berlin, Germany. • Your investigation site (contact details see above).

2. Data protection officer

For any question about the processing of your data, we recommend that you first contact your investigator. However, you also have the right to contact the data protection officer of the sponsor's delegate:

BIOTRONIK SE & Co. KG
Data Protection Officer
Woermannkehre 1
12359 Berlin
Germany

Please be aware that by using this contact you disclose your identity and additional personal data (e.g. your address) to the sponsor of the study.

3. Purpose and details on the processing of personal data

(a) For the purpose of this study personal data will be processed to the extent necessary, which may include basic patient information such as name, contact details, age and sex. Additionally more specific information will be processed, such as diagnostic information, device data, information on side effects and other adverse events, data from cardiologic and physiological examinations, which qualify as special categories of data, e.g. **data concerning health**. Such data will be processed by the investigation site. To the extent necessary data will be pseudonymised and thus transferred to

- BIOTRONIK, the sponsor of the clinical study, its affiliated companies and/or to a contractually bound service provider/designee for data analysis in a scientific context.
- the responsible federal state authority (if applicable) in case of the occurrence of adverse events.

(b) For the purpose of this study BIOTRONIK also uses pseudonymised data transferred by the BIOTRONIK Home Monitoring system and ReportShare.

(c) Authorised BIOTRONIK representatives, obliged to confidentiality, as well as competent authorities will be granted access to the patients' medical records by the treating physicians as far as this is necessary for conduct of the study.

(d) Pseudonymised data, collected during the time of study participation will also be processed by BIOTRONIK for medical technological research purposes and for research in the field of cardiology and to

- analyse the outcome, efficacy and residual safety aspects of cardiac rhythm monitoring.
- to identify areas of improvement for cardiac rhythm management and ICM devices.
- support market authorisations for current and future BIOTRONIK products.

For the purpose of additional analyses outside the scope outlined above BIOTRONIK will anonymise the data.

4. Transfer of personal data to other countries

For this study, the pseudonymised data will be processed using a secure and validated electronic system, maintained by the certified service provider MedNet Solutions, Inc., USA. During the study the pseudonymised data is stored in the USA at MedNet Solutions, Inc., and will then be transferred to the BIOTRONIK SE & Co KG, Germany. However, a data protection level that is similar to European standards is ensured by standard data protection clauses which are contractually agreed between BIOTRONIK and MedNet Solutions Inc., as required by European law.

5. Period of data storage / deletion of data

The data will be stored and archived after termination of the clinical study over the period stipulated by law (currently 15 years). After the archiving period the data may be deleted if not otherwise indicated by legal, statutory or contractual regulations for record retention. Archiving of the personal data over the period stipulated by law will not occur in case you withdraw your consent, unless you have explicitly agreed to the further use of your already collected pseudonymised data.

6. Rights of the data subject

Every participating patient (data subject) has the following rights:

(a) the right to withdraw the consent to data processing at any time. The withdrawal does not affect the lawfulness of processing based on consent before its withdrawal. In case consent shall be withdrawn, please contact your investigation site (contact details see above). The patient will have the option to consent to the further use of already collected pseudonymised data after the withdrawal.

(b) the right to access personal data;

(c) the right to rectification, erasure or to restriction of processing of your personal data;

(d) the right to data portability;

(e) the right to lodge a complaint with a supervisory authority;

(f) the right to object at any time to processing of your personal data.

If you have any questions regarding the use of data and the protection of privacy please contact your physician.

15 Complaints and compensation

If you suffer from any injuries or complications as a result of this study, you should contact the study doctor or study team (as outlined in section 18) as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

Participation in this study does not impact on your basic legal right to seek compensation; however, if you do suffer harm, you may receive compensation without litigation.

The Sponsor of this study agrees to follow the Medicines Australia Guidelines for Compensation for Injury resulting from participation in an Industry-sponsored Clinical Trial. These Guidelines allow for some claims for compensation to be settled without the need for legal action to be taken. You can obtain a copy of these Guidelines from the study team on request.

Insurance

In case of damages caused to your health by participation in the study, you are insured with the VERO insurance company in accordance with Australian legislation (insurance policy number LPP010537382). This insurance is based on legal obligations and not on the expectation of occurrence of damage. The insurance does not cover damages that do not have direct correlation to the study. Any insurance claim you make is in addition to any rights to compensation as outlined in Section15, “Complaints and Compensation”.

You have to adhere to the following rules in order to avoid compromising your insurance coverage:

- Strictly adhere to the instructions given by your study doctor, [Name of local Principal Investigator] and his/her personnel.
- In case of an emergency it is very important that you inform your study doctor about the event without delay.

You should contact your study doctor in case of any damage to your health that might have occurred as a consequence of your participation in the study.

16 Who is organising and funding the research?

This study is being conducted by *[insert Name of local Principal Investigator]*.

This study is being conducted and sponsored by BIOTRONIK Australia Pty Ltd and is being conducted and funded by BIOTRONIK SE & Co. KG.

BIOTRONIK may benefit financially from this study if, for example, the project assists BIOTRONIK Australia Pty Ltd to obtain full approval for the new device.

[Insert Name of Institution] will receive a payment from BIOTRONIK for undertaking this study. This payment is to cover administrative costs of running the project.

No member of the research team will receive a personal financial benefit from your involvement in this study (other than their ordinary wages).

There are no declarations of interest of the study doctors.

17 Who has reviewed the study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the Metro South HREC of the Princess Alexandra Hospital, Woolloongabba, Brisbane.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

18 Further information and who to contact

A description of this clinical trial will be available on www.ANZCTR.org.au. This website will not include information that can identify you. At most, the website will include a summary of the results. You can consult the general outcome and results of this study after they have been made publicly available by consulting this website.

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact any of the following people:

Principal Investigator:

Name	<PI's name>
Telephone	<PI's details>
E-mail	<E-mail may be added if it is an institutional requirement or deleted>

Study team clinical contact person: (to be used by site if applicable, can be deleted if not applicable, delete this statement and table if not used)

Name	<Study team's name>
Position	<Study member's position>
Telephone	<Study team details>
E-mail	<E-mail may be added if it is an institutional requirement or deleted>

Complaints contact person:

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Name	<Site's complaint person's name>
Position	<Site's complaint person's position>
Telephone	<Site's complaint person's details>
E-mail	< E-mail may be added if it is an institutional requirement or deleted >

Reviewing HREC approving this research and HREC Executive Officer details:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a study participant in general then you may contact:

Reviewing HREC name	Metro South Human Research Ethics Committee

Telephone	3443 8049
E-mail	MSH-Ethics@health.qld.gov.au

Consent Form

Title	BIO|CONCEPT.BIOMONITOR III
Short Title	BM3CONCEPT
Protocol Number	RD020
Project Sponsor	BIOTRONIK Australia
Principal Investigator	*[Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]* **<Associate Inv's details if required by institution – delete if not required>**
Location	*[Location]*

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[insert Name of Institution]* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I have been informed that personal data will be processed in terms of this clinical investigation. The data will only be processed in accordance with the applicable statutory regulations. This presupposes a voluntarily given consent. Study participation is only possible after I have given my consent to data processing. I have been provided with the information about data protection in the Data Protection Statement in Section 14.

I understand that I will be given a signed copy of this document to keep.

Optional:

☐ **Yes** I also give consent for the sponsor to record the insertion of the investigational

☐ **No** device with a video camera. Only the uncovered chest will be recorded.

(please mark with a cross where applicable)

Name of Participant	Signature of Participant	Personally Dated

<If your site requires a witness to be added to the PICF then please add this here. Remove this statement if witness not required>

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor†

I have given a verbal explanation of the study, its procedures and risks and I believe that the participant has understood that explanation.

Name of Investigator	Signature of Investigator	Personally Dated

† *A medical member of the research team must provide the explanation of and information concerning withdrawal from the research project.*
Note: All parties signing the consent section must date their own signature

Form for Withdrawal of Participation

Title	BIO|CONCEPT.BIOMONITOR III
Short Title	BM3CONCEPT
Protocol Number	RD020
Project Sponsor	BIOTRONIK Australia
Principal Investigator	*[Principal Investigator]*
Associate Investigator(s)	*[Associate Investigator(s)]* **<Associate Inv's details if required by institution – delete if not required>**
Location	*[Location]*

Declaration by Participant

I wish to withdraw from participation in the above study and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[insert name of Institution]*.

Name of Participant	Signature of Participant	Personally Dated

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor†

I have given a verbal explanation of the implications of withdrawal from the study and I believe that the participant has understood that explanation.

Name of Investigator	Signature of Investigator	Personally Dated

† *A medical member of the research team must provide the explanation of and information concerning withdrawal from the study.*