

EXHIBIT “F”
CLAIMS ELIGIBILITY CRITERIA, COMPENSATION AND
ADMINISTRATION PROCEDURES

1. CLAIMS ELIGIBILITY CRITERIA AND SUPPORTING DOCUMENTATION

- 1.1. In order to be eligible for compensation under the Settlement Agreement, each Claimant must provide evidence of the Class Member’s implantation **AND** premature explantation/replacement of one of the following Defibrillators:

Defibrillator	Model	Manufactured Before
Marquis VR	7230	December 31, 2003
Marquis DR	7274	December 31, 2003
Maximo VR	7232	December 31, 2003
Maximo DR	7278	December 31, 2003
InSync Marquis	7277	December 31, 2003
InSync III Marquis	7279	December 31, 2003

- 1.2. In order to establish that the Class Member was implanted with one of the Defibrillators, a submitted Claim Package must include one of the following:

- a) if the Class Member received a Certification Notice Letter, the signed solemn declaration contained in the Claim Form attesting to the fact that the Class Member had previously received a Certification Notice Letter; **or**
- b) a photocopy of the Class Member’s Medtronic Implanted Pacer-Cardioverter-Defibrillator ID Card which reflects the Defibrillator Type, Model and Implant Date; **or**
- c) one of the following medical records which reflects the Class Member’s Defibrillator Type, Model and Implant Date, including, but not limited to:
 - i. a Medtronic Quick Look Report; **or**
 - ii. an operative report describing the Class Member’s implantation with one of the Defibrillators, including the Type, Model and Implant Date; **or**

- iii. any other medical record reflecting the Class Member's implantation with one of the Defibrillators, which record must include the Defibrillator Type, Model and Implant Date.
- 1.3. In order to be eligible for compensation under the Settlement Agreement, it must be established that the Class Member's Defibrillator was **prematurely** explanted/replaced **as a result of** the Health Canada advisory (recall) issued in February, 2005.
- 1.4. To establish that a Class Member's Defibrillator was prematurely explanted/replaced as a result of the recall, one of the following must be included with the Claimant's Claim Package:
- a) if the Class Member's defibrillator was explanted/replaced between February 1, 2005 and August 31, 2005, the operative report from the hospital where the Defibrillator was explanted/replaced; **or**
 - b) if the Class Member's defibrillator was explanted/replaced on or after September 1, 2005, medical records reflecting the explant/replacement procedure which contains a contemporaneous medical opinion stating that the explant/replacement was a result of the recall; **or**
 - c) if the Class Member's defibrillator was explanted/replaced on or after September 1, 2005 and the explant/replacement records do not include any medical opinion attributing the explant/replacement to the recall, a completed and signed Physician Declaration, as contained in the Claim Package.
- 1.5. In order to be eligible for compensation from the Extraordinary Injury Fund, a Claimant must satisfy the criteria set out above **and** must also establish that the Class Member suffered from either Minor or Major Complications as set out below **within 45 days** of the premature explant/replacement of their Defibrillator.
- 1.6. For the purposes of this Settlement, Minor Complications shall include any one or more of the following:
- a) Hematomas lasting more than 7 days with tenseness, drainage, or minor dehiscence managed as an outpatient;
 - b) Hematomas without tenseness be requiring additional outpatient evaluation;
 - c) Implant related pain lasting more than 7 days requiring prolonged use of narcotic pain medications;

- d) Cellulitis treated as an outpatient with oral antibiotics;
- e) Stitch abscess;
- f) Minor surgical wound findings;
- g) Unanticipated device reprogramming resulting from inadequate lead performance with significant patient symptoms or status change, excluding asymptomatic threshold changes;
- h) Reversal of sedation for respiratory compromise requiring benzodiazepine or opioid receptor antagonist;
- i) Peripheral nerve injury; or
- j) Superficial phlebitis.

1.7. For the purposes of this Settlement, Major Complications shall include any one or more of the following:

- a) Pneumothorax requiring observation or chest tube placement;
- b) Hemothorax;
- c) Stroke within 45 days of the explant/replacement procedure;
- d) Hemodynamic instability during the procedure requiring unplanned intervention and/or aborting the procedure;
- e) Infection requiring intravenous antibiotics and/or system removal/extraction;
- f) Generator or lead malfunction requiring reoperation;
- g) Pocket revision requiring reoperation;
- h) Prolonged hospitalization attributable to the device replacement procedure;
- i) Hematoma requiring evacuation, drainage, blood transfusion, hospitalization, or extension of hospital stay to treat hematoma;
- j) Hospital readmission directly related to the explant/replacement procedure;
- k) Coronary venous dissection with hemodynamic instability;
- l) Pulmonary embolus;
- m) Peripheral arterial embolus;
- n) Deep vein thrombosis;
- o) Drug reaction resulting in an aborted procedure;
- p) Cardiac valve injury; or

- q) New atrioventricular conduction block developing as a result of the procedure.
- 1.8. In order to establish that a Class Member suffered from a Minor and/or a Major Complication, the Claimant must complete the relevant sections of the Claim Form as contained in the Claim Package, and submit medical records reflecting the Class Member's treatment/diagnosis related to the Minor and/or Major Complication(s) suffered by the Class Member within 45 days of the premature explant/replacement procedure.
 - 1.9. If a Claimant is seeking compensation related to the Class Member's out-of-pocket expenses and/or wage loss, details must be provided in the relevant sections of the Claim Form, along with supporting documentation reflecting any such loss(es).

2. COMPENSATORY PAYMENTS AND PAYMENT SCHEDULE

- 2.1. Claimants with Approved Claims shall be entitled to a maximum Compensatory Payment in the amount of \$5,000.00 CDN, which is inclusive of all claims of Family Class Members, out-of-pocket expenses, and income losses, which may be subject to a *pro rata* reduction, depending on the total number of Approved Claims.
- 2.2. If the total value of all Approved Claims exceeds 80% of the amount remaining in the Escrow Settlement Funds following the payments set out in Sections 8.2 and 8.3 of the Settlement Agreement, the Claims Administrator shall reduce the value of all Approved Claims on a *pro rata* basis.
- 2.3. If the total value of all Approved Claims is less than 80% of the amount remaining in the Escrow Settlement Funds following the payments set out in Sections 8.2 and 8.3 of the Settlement Agreement, the excess money shall be available to top up Extraordinary Injury Fund Awards, if those have been reduced in accordance with s.2.7 below. If there has been no reduction applied to the Extraordinary Injury Fund Awards, 50% of the Residue shall be allocated *pari passu* among all Approved Claims and 50% shall be paid to Class Counsel in trust for the benefit of the Public Health Insurers, to be distributed among the Public Health Insurers on a population distribution basis.
- 2.4. If the Claims Administrator determines that a Class Member with an Approved Claim also suffered Minor or Major Complication(s), an award shall be recommended by the Claims Administrator and confirmed or modified by Class Counsel based on the severity of the complication(s) and any proven out-of-pocket expenses and/or wage loss.

- 2.5. Claimants shall only be eligible for one award from the Extraordinary Injury Fund, regardless of the number of Minor or Major Complications the Class Member may have suffered and proven. The Claimant shall receive the award for the most severe Complication deemed proven.
- 2.6. If the total value of all Extraordinary Injury Fund awards exceeds 20% of the amount remaining in the Escrow Settlement Funds following the payments set out in Sections 8.2 and 8.3 of the Settlement Agreement, the Claims Administrator shall reduce the value of all Extraordinary Injury Fund Awards on a *pro rata* basis.
- 2.7. If the total value of all assessed Extraordinary Injury Fund Awards is less than 20% of the amount remaining in the Escrow Settlement Funds following the payments set out in Section 8.2 and 8.3 of the Settlement Agreement, such funds shall be allocated to increase the value of Approved Claims if the value of same has been reduced in accordance with Section 2.2 and if there has been no such reduction in the value of Approved Claims, 50% of the remaining funds shall be allocated *pari passu* among all Approved Claims and 50% shall be paid to the Public Health Insurers, to be distributed among them on a population distribution basis.
- 2.8. No payment shall be issued to any Claimant until the Claims Administrator has adjudicated all Claims submitted during the Claim Period and has determined whether any adjustments are required in accordance with Sections 2.2, 2.7, or 2.8 above are necessary, after which, the Claims Administrator shall deliver Claim Determination Letters to all Claimants enclosing cheques for all Approved Claims.
- 2.9. The determinations of the Claims Administrator as approved or modified by Class Counsel on all Claims are final and binding and shall not be subject to further review.

3. OVERVIEW OF SETTLEMENT ADMINISTRATION

- 3.1. The procedures set forth herein are for the administration of the Settlement Agreement and for the submission, processing, approval or denial, compensation, and review of Class Members' claims pursuant to the Settlement Agreement. These procedures shall be implemented by the Claims Administrator, subject to the ongoing authority and supervision of the Court.
- 3.2. The Claims Administrator may adopt additional policies and procedures for the administration of the Settlement Agreement that are consistent with the Settlement Agreement and with any Orders of the Court. Any change or amendment to these Claims Administration Procedures requires approval of the Court.

- 3.3. The Claims Administrator shall implement the Settlement Agreement so as to provide benefits to eligible Claimants in a timely and efficient manner, designed to treat similarly situated Claimants as uniformly as possible and to minimize, to the extent reasonably practicable, the administration and other transaction costs associated with the implementation of the Settlement Agreement.
- 3.4. The Claims Administrator shall provide copies of any written communication to or from the Claims Administrator relating in any way to this settlement to Plaintiffs' Counsel. Any counsel entitled to receive copies of such written communication under this provision may waive that entitlement by so advising the Claims Administrator. The Claims Administrator shall also provide "read-only" access to the claims administration computer system to Plaintiffs' Counsel.
- 3.5. All defined terms are as defined in the Settlement Agreement or herein. All calculations of time and deadlines pursuant to these Claims Administration Procedures shall be calculated in accordance with the Ontario *Rules of Civil Procedure* which are available at www.e-laws.gov.on.ca as Regulation 194 to the *Courts of Justice Act* R.S.O. 1990, c. C.43.

4. ROLES IN CLAIMS ADMINISTRATION

Role and Appointment of the Claims Administrator

- 4.1 RicePoint Administration Inc. ("RicePoint") shall be appointed by the Court as the Claims Administrator and shall be responsible for holding, investing and disbursing the Escrow Settlement Funds in accordance with the terms of the Settlement Agreement and the Escrow Agreement.
- 4.2 RicePoint shall invest all funds in its possession under the Settlement Agreement pursuant to the investment standards and authorized investments provided for in section 27 of the *Trustee Act*, R.S.O. 1990, c.T.23 with all interest or other income on such funds being added to the monies in trust as set out in the Settlement Agreement. All fees and costs of any custodian holding and/or investing such funds shall be paid out of such funds or out of the interest and/or income of such funds.
- 4.3 RicePoint shall take all reasonable steps to minimize the imposition of taxes upon the Escrow Settlement Funds, and shall have the discretion to pay any taxes imposed on such monies out of the monies in the Escrow Account.
- 4.4 Disbursement of any monies out of the Escrow Settlement Funds in the Escrow Account shall only be made in accordance with the Settlement Agreement or upon directions issued by the Court.
- 4.5 RicePoint shall provide quarterly written reports to Plaintiffs' Counsel, as well as reporting on such other matters as may be requested by the Court.

In addition, Plaintiffs' Counsel may request reports or information not required by the Settlement Agreement. RicePoint shall respond to any such request within seven (7) days

4.6 In addition, RicePoint shall be responsible for:

- (i) providing adequately trained, supervised and monitored personnel in such reasonable numbers as are required for the performance of its duties within reasonable timeframes;
- (ii) setting up and maintaining a system for the handling of queries from Class Members and Claimants in both English and French, including a bilingual toll-free telephone line and web site;
- (iii) preparing and distributing Claim Packages in both French and English;
- (iv) developing, installing and implementing systems and procedures for receiving and processing Claim Packages, determining the completeness of Claim Packages and delivering Deficiency Letters to Claimants, and adjudicating Claims in a timely manner and in accordance with the terms of the Settlement Agreement and related Exhibits and delivering Determination Letters to Claimants;
- (v) forwarding payment to qualified Claimants;
- (vi) reporting as required by the Settlement Agreement, including reporting on a quarterly basis with respect to the implementation of the Settlement generally, and, without limiting the generality of the foregoing, providing information as to the number of Claim Packages received, the number of claims processed, the type of claims processed, the total amount of money distributed, the amount of money remaining in the Escrow Settlement Funds, the interest accrued, the number of Deficiency Letters delivered and the number of Claim Determination Letters delivered;
- (vii) making such minor modifications to the Claim Package as may be necessary for the implementation of the Settlement Agreement, however, any substantive change or amendment to these forms requires approval of the Court;
- (viii) co-ordinating with Plaintiffs' Counsel and holding regular administrative conference calls to advise them of the progress of the administration of the Settlement. In addition, when deemed necessary by the Claims Administrator, calling special meetings on reasonable notice to all Parties; and

- (ix) such other duties and responsibilities as the Court may from time to time direct.

5. CLAIM PACKAGE REQUIREMENTS

General Provisions

- 5.1. A completed Claim Package in the form attached as Exhibit G to the Settlement Agreement shall include a completed and signed Claim Form, along with all required supporting documentation as identified herein and as set out in the Claim Package.
- 5.2. Qualification for benefits pursuant to the Settlement Agreement requires the timely filing with the Claims Administrator of a complete Claim Package and all related documentation. The Claims Administrator shall review all Claim Packages submitted within the Claim Period for sufficiency within thirty (30) days of receipt.
- 5.3. If an incomplete Claim Package is submitted by a Claimant, the Claims Administrator shall advise the Claimant of any such deficiency by delivering a letter to the Claimant, indicating what deficiencies exist (a "Deficiency Letter") and requiring that the Claimant cure the deficiency/ies within forty five (45) days of the mailing of the Deficiency Letter.
- 5.4. The Claimant shall have the option, but shall not be required to, cure the deficiency(ies) identified by the Claims Administrator through providing more complete information and/or obtaining and submitting further documentation, as the case may be.
- 5.5. Once the forty five (45) day curing period has expired, the Claims Administrator shall determine the claim (whether or not any identified deficiency has been cured by the Claimant) and determine the Claimant's eligibility under the Settlement Agreement.

Claim Form

- 5.6. The Claim Form shall be completed and signed by the Claimant and must include information regarding the identity, the address and other contact information for the Claimant (or his/her representative), along with the requisite documentation and/or declaration(s) confirming the Class Member's implant and establishing that the Class Member had one of the Defibrillators prematurely explanted/replaced as a result of the recall.
- 5.7. Where a Claimant is seeking compensation from the Extraordinary Injury Fund, the relevant section(s) of the Claim Form must be completed by the

Claimant and the requisite supporting documentation must be submitted, confirming the Class Member's Minor and/or Major Complication(s).

- 5.8. Where a claim is filed on behalf of a deceased Class Member, it must be filed by an executor or other person with the legal authority to administer the Class Member's estate and documentary proof of that legal authority must be submitted with the Claim Package.
- 5.9. Where a claim is filed for a Class Member under a legal disability, it must be filed by an individual with appropriate legal authority to represent the disabled Class Member and documentary proof of his or her legal authority to act on behalf of the Class Member must be submitted with the Claim Package.

6. PROCESSING OF CLAIMS

Review of Claim Packages

- 6.1 Upon receipt of a Claim Package, the Claims Administrator shall deliver a letter to the Claimant within seven (7) days, acknowledging receipt of the Claim Package (the "Acknowledgement Letter", Exhibit H to the Settlement Agreement) and shall assign an individual claim number to the Claim Package and post the contents of the Claim Package on the Claims Administrator's claims administration system. Read-only access via a secure website to the claims administration system shall be granted to Plaintiffs' Counsel. Plaintiffs' Counsel shall also be entitled to obtain hard copies of a specified Claim Package, or any part thereof, upon request to the Claims Administrator.
- 6.2 Within thirty (30) days of receipt, the Claims Administrator shall review the Claim Package to ensure that:
 - (a) It includes a completed and signed Claim Form;
 - (b) It includes any/all necessary declaration(s) and/or supporting medical documents;
 - (c) It includes any other documentation required by the terms of the Settlement Agreement (i.e. proof of executorship, guardianship, relationship with a Class Member, etc.); and
 - (d) It was received by RicePoint within the Claim Period.
- 6.3 Where the Claim Package is deemed to be incomplete, RicePoint shall, within seven (7) days of such determination, so advise the Claimant in a Deficiency Letter (Exhibit I to the Settlement Agreement). The Deficiency Letter shall advise the Claimant as to the deficiencies in the Claim Package and shall provide the Claimant with a further forty five

(45) days within which the Claimant has the right to cure any such deficiencies.

- 6.4 Where the Claim Package is deemed to be complete and/or after the time for curing deficiencies has elapsed, the Claims Administrator shall review the Claim Package to determine whether the Class Member is eligible for compensation under the Settlement Agreement.
- 6.5 Within ninety (90) days following the final adjudication of all submitted Claims, RicePoint shall deliver Claim Determination Letters (Exhibit J to the Settlement Agreement) to all Claimants, enclosing cheques for all Claimants with Approved Claims. All decisions of RicePoint on the eligibility and quantification of Claims, as confirmed or modified by Class Counsel, are final and not subject to review.

7. MISCELLANEOUS

Timeliness of Submissions

- 7.1. All Claim Packages shall be submitted to the Claims Administrator via regular mail, electronic mail, or courier, or by any other means agreed to by the Parties and the Claims Administrator. All submissions by mail shall be conclusively deemed to have been submitted to the Claims Administrator on the postmark date of such mail. All Claim Packages delivered to the Claims Administrator by courier shall be conclusively deemed to have been submitted to the Claims Administrator on the date of the receipt by the Claims Administrator of such submissions. Where the Claims Administrator and the Parties agree to an alternative means of submission, the date of receipt by the Claims Administrator shall be conclusively deemed to be the date of submission.
- 7.2. In order to qualify for compensation, Claimants must submit their Claim Packages prior to the expiration of the Claim Period.
- 7.3. In the event that the Claims Administrator receives a Claim Package after the expiration of the Claim Period, the Claims Administrator shall process the Claim Package in the ordinary course only upon the Claimant establishing good cause for the late submission, the determination of which rests exclusively with the Claims Administrator.

Extension of Deadlines

- 7.4. In the event that any of the deadlines prescribed herein relating to the administration and processing of claims cannot be met, a motion may be

made to the Court for directions which may allow for the extension of such deadlines in circumstances where such extensions are demonstrably justifiable. Any such motion must be made on notice to all Parties.

- 7.5. In the event that any deadline for the administration or determination of claims is not met by the Claims Administrator, such an event shall not affect give rise to a right of challenge by a Claimant and shall not affect any Claimant's entitlement to benefits pursuant to the Settlement Agreement.

Call Centre

- 7.6. The Claims Administrator shall establish a bilingual toll-free call centre for the assistance of Claimants and to provide Claimants with information on the status of their claims.

Website

- 7.7. The Claims Administrator shall establish a bilingual website for the assistance of Claimants.

Correspondence with Class Members

- 7.8. All written communications from the Claims Administrator to Claimants shall be delivered by regular mail, unless instructed by the Claimant to communicate via electronic mail. The Claims Administrator shall direct such written communications to the Claimant's legal counsel if the Claimant is represented by counsel, otherwise, such written communications shall be directed to the last known address provided by the Claimant to the Claims Administrator. The Claimant (or legal counsel to a represented Claimant) shall be responsible for apprising the Claims Administrator of the Claimant's and counsel's correct and current mailing and/or electronic address.

Legal Counsel to Claimants

- 7.9. A Claimant shall be considered to be represented by legal counsel in connection with a claim only if the Claims Administrator has received written notice signed by the Claimant of the identity of the Claimant's counsel. If a Claimant discontinues such representation at any time the Claimant shall provide written notice of same to the Claims Administrator and their former counsel.
- 7.10. No liens or claims for counsel fees or costs may be asserted against the Claims Administrator or the funds held by the Claims Administrator at any time.

Preservation and Disposition of Claim Packages

- 7.11. The Claims Administrator shall preserve, in hard copy or electronic form, as the Claims Administrator deems appropriate, the Claim Packages, until a date one (1) year following the completion of all payments out of the Escrow Settlement Funds and at such time shall dispose of the Claim Packages by shredding or such other means as will render the materials permanently illegible.

Privacy of Communications

- 7.12. Any information provided by or regarding any Class Member or Claimant, or such information otherwise obtained pursuant to this Settlement shall be kept confidential and shall not be disclosed except to appropriate persons to the extent necessary to process claims or provide benefits pursuant to this Settlement or as otherwise expressly provided in the Settlement Agreement. All Claimants shall be deemed to have consented to the disclosure of this information for these purposes.