

## **SILZONE® PRODUCT SETTLEMENT CLAIM FORM**

**COMPLETE THIS FORM IF THE FOLLOWING APPLY:**

- 1. You were a British Columbia resident on December 2, 2009 and you were implanted in British Columbia or elsewhere with a St. Jude Medical mechanical heart valve with a sewing cuff coated with Silzone® or an annuloplasty ring coated with Silzone®, or**
  
- 2. You are one of a family member, heir or executor of the estate of a person who was a British Columbia resident at the time of his or her death prior to December 2, 2009 and who was implanted in British Columbia or elsewhere with a St. Jude Medical mechanical heart valve with a sewing cuff coated with Silzone® or an annuloplasty ring coated with Silzone®; and**
  
- 3. You wish to make a claim for compensation in this class action.**

**NOTE: All parts of this Claim Form must be completed in order to be eligible to recover settlement funds. This includes Part 1 (Claimant's Name and Contact Information); Part 2 (Claim Category); Part 3 (Medical Doctor's Statement); and Part 4 (Declaration). In order for you to be eligible to recover, the completed Claim Form must be received by Poyner Baxter LLP before 4:00 p.m., June 30, 2010. Poyner Baxter's address and fax number are listed at the end of this Claim Form.**

**PART 1: CLAIMANT'S NAME AND CONTACT INFORMATION**

**Name of Claimant:** \_\_\_\_\_

**Name of B.C. resident implanted with the Silzone® Product** (if different than name of Claimant) \_\_\_\_\_

**If B.C. resident implanted with the Silzone® Product is deceased, the date and place of death.** Date: \_\_\_\_\_  
Place: \_\_\_\_\_

**Name of Parent or Guardian** \_\_\_\_\_  
(If Claim Form is being completed on behalf of a minor or a person under a disability)

**Mailing Address:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Phone Number:** Business: \_\_\_\_\_  
Home: \_\_\_\_\_

**E-mail address (if any)** \_\_\_\_\_

**PART 2: CLAIM CATEGORY**

The following definitions apply in determining your claim category:

“B.C. Class member” means a person who was a British Columbia resident on December 2, 2009 and who was implanted in British Columbia or elsewhere with a mechanical heart valve or annuloplasty ring coated with Silzone® which was designed, manufactured, marketed, distributed, or sold by the Defendants (“Silzone® Products”) and a deceased person, who at the time of his death (prior to December 2, 2009) was a B.C. resident and who was implanted in British Columbia or elsewhere with a mechanical heart valve or annuloplasty ring coated with Silzone® which was designed, manufactured, marketed, distributed, or sold by the Defendants.

“Settlement Class” means the Plaintiff and all B.C. Class members who do not validly opt out of the B.C. Class in accordance with the opt-out procedure set out in Section C(2) of the Settlement Agreement.

“Settlement Class Member” means a member of the Settlement Class.

“Silzone® Product” means a St. Jude Medical mechanical heart valve with a sewing cuff coated with Silzone® or an annuloplasty ring coated with Silzone®.

“Major Paravalvular Leak (“Major PVL”) means leakage around the Silzone® Product which occurs in the absence of infection and which results in re-operation or re-intervention for repair, explant or death, occurring 30 days or more after implantation of the Silzone® Product or such re-intervention is recommended but is refused by the B.C. Class Member or cannot be performed due to co-morbidity or other reasons.

“Minor Paravalvular Leak (“Minor PVL”) is a leakage around the Silzone® Product occurring 30 days or more after implantation of the Silzone® Product occurring in the absence of infection which is determined by the use of echocardiogram (color flow Doppler) and does not require surgery.

The degree of Minor PVL is determined, in the case of mitral valve recipients, by calculation of the ratio of maximum regurgitant jet area/left atrial area, and, in the case of aortic valve recipients, by calculation of the proximal jet width/left ventricular outflow tract diameter obtained from the parasternal long-axis view. Minor PVL is classified as mild, moderate or severe as follows:

- A. Mild:
  - (i) for mitral valve recipients, a ratio of less than 20 percent;
  - (ii) for aortic valve recipients, a ratio of less than 24 percent;
- B. Moderate:

- (i) for mitral valve recipients, a ratio between 20 and 40 percent;
- (ii) for aortic valve recipients, a ratio between 25 and 64 percent

C. Severe:

- (i) for mitral valve recipients, a ratio of more than 40 percent;
- (ii) for aortic valve recipients, a ratio of 65 percent or more.

“Psychological Injury” means a diagnosable adjustment disorder with anxiety or an anxiety disorder, as defined in the Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition, Text Revision (“DSM – IV”), as a result of learning about the recall of the Silzone coated valve (and not just as a result of the implant of the valve or any other disease process). The severity of the disorder is categorized as Mild Disorder, Moderate Disorder and Severe Disorder as described in Schedule “H”.

Only one Claim Form can be submitted for or on behalf of each Settlement Class Member.

If a Settlement Class Member is deceased and died prior to December 2, 2009, only one of a family member, heir or executor may submit a claim for compensation of \$500.00.

If a deceased Settlement Class Member was diagnosed with Major PVL then only one of a family member, heir or executor of the deceased’s estate may submit a claim against the Compensatory Fund for Major PVL and for compensation from the Income Loss Fund.

If a deceased Settlement Class Member was diagnosed with a Psychological Injury then only one family member, heir or executor of the deceased’s estate may submit a claim against the Psychological Injury Fund.

Place an “X” in the category or categories which apply to you:

I was implanted with a Silzone® Product (mark X if correct):

I was a British Columbia resident on December 2, 2009 (mark X if correct):

I am a family member, heir, or executor of the estate of a person implanted with a Silzone® Product who was a B.C. resident at the time of death and died on \_\_\_\_\_ (mark X if correct):

I have been diagnosed with Mild Minor PVL of the mitral heart valve (mark X if correct):

I have been diagnosed with Moderate Minor PVL of the mitral heart valve (mark X if correct):

I have been diagnosed with Severe Minor PVL of the mitral heart valve (mark X if correct):

I have been diagnosed with Mild Minor PVL of the aortic heart (mark X if correct):

valve

I have been diagnosed with Moderate Minor PVL of the aortic heart valve (mark X if correct):

I have been diagnosed with Severe Minor PVL of the aortic heart valve (mark X if correct):

I have been diagnosed with Major PVL (mark X if correct):

The deceased Settlement Class Member was diagnosed with Major PVL (mark X if correct):

I have been diagnosed with Psychological Injury  
Mild:   
Moderate:   
Severe:

The deceased Settlement Class Member was diagnosed with Psychological Injury  
Mild:   
Moderate:   
Severe:

I suffered income loss as a result of developing Major PVL, Minor PVL or a Psychological Injury (mark X if correct):

The deceased Settlement Class Member suffered income loss as a result of developing Major PVL, Minor PVL or a Psychological Injury (mark X if correct):

NOTE: While multiple categories may apply, Claimants obtaining compensation for Major PVL are not eligible for compensation for Minor PVL.

**PART 3: MEDICAL INFORMATION**

1. The Settlement Class Member or one family member, heir or executor of the estate of a deceased Settlement Class Member seeking compensation at the \$500.00 level (that is: no claim for compensation for either Major or Minor PVL) must only submit the Settlement Class Member's medical records showing that he or she was implanted with a Silzone® Product.
2. A Settlement Class Member seeking compensation for Major PVL or one family member, heir or executor of the estate of a deceased Settlement Class Member seeking compensation on behalf of the deceased Settlement Class Member for Major PVL must submit echocardiogram results taken more than 30 days post implantation of a Silzone® Product and medical records documenting re-operation or re-intervention for repair, explant or death resulting from Major PVL occurring thirty (30) days or more after the implantation of a Silzone® Product or that such re-operation or re-intervention was recommended but was refused by the Settlement Class Member or could not be performed due to co-morbidity or other reasons. A statement from a cardiac surgeon or cardiologist must be provided stating that the re-operation or re-intervention was necessary to treat Major PVL or that such re-operation or re-intervention was recommended but was refused by the Settlement Class Member or could not be performed due to co morbidity or other reasons. Where the Settlement Class Member died as a result of Major PVL an autopsy report indicating that death resulted from Major PVL may be provided in lieu of the statement from a cardiac surgeon or cardiologist.
3. Settlement Class Members seeking compensation for Minor PVL must submit echocardiogram results taken thirty (30) days or more post implant of the Silzone® Product together with a declaration from a cardiologist stating that the Minor PVL occurred thirty (30) days or more post implant and whether such Minor PVL is Mild, Moderate or Severe Minor PVL according to the criteria set out above in Part 2.
4. Settlement Class Members seeking compensation for Psychological Injury or one family member, heir or executor of the estate of a deceased Settlement Class Member seeking compensation on behalf of the deceased Settlement Class Member for Psychological Injury must submit the following:
  - (a) A declaration by the Settlement Class Member as to the date he or she first learned of the recall of the Silzone coated valve;
  - (b) A declaration from a general physician, psychiatrist or psychologist confirming that the Settlement Class Member experienced a diagnosable adjustment disorder with anxiety or an anxiety disorder, as set out in Schedule "H" to this Settlement Agreement. The declaration will include a statement as to the severity of the disorder based on Axis V of the DSM – IV – the Global Assessment of Functioning score - and whether the Class Member's score was:
    - (i) greater than 60

- (ii) between 51 and 60
  - (iii) less than 51.
- (c) The declaration will also include a statement as to how long the disorder continued, based on the following categories:
  - (i) less than 6 months
  - (ii) 6 months to 18 months
  - (iii) more than 18 months.
- (d) In the case where the declaration in 4(b) above is by a general physician, contemporaneous medical records evidencing that, between the date the Settlement Class Member learned of the recall and the date one year thereafter, the Settlement Class member sought medical attention as a result of the recall of the Silzone valve from his or her physician, psychiatrist or psychologist, for and was diagnosed with the onset of an adjustment disorder or an anxiety disorder falling in the DSM-IV and was treated with psychotherapy and or appropriate medication.

**PART 4: INCOME LOSS CLAIM INFORMATION**

1. A Settlement Class Member who suffered income loss as a result of Major or Minor PVL and seeking compensation from the Income Loss Fund must provide a report from his or her cardiac surgeon or cardiologist stating that:
  - (a) he or she was unable to work as a result of suffering Major PVL, Minor PVL or a Psychological Injury; and
  - (b) the period of time he or she was unable to work as a result of suffering Major PVL, Minor PVL or a Psychological Injury.
  
2. A Settlement Class Member seeking compensation from the Income Loss Fund must submit:
  - (a) a statement of work history for the 3 years prior to being diagnosed with Major PVL, Minor PVL or a Psychological Injury for the 2 years following such diagnosis; and
  - (b) Income Tax returns for the 3 years prior to being diagnosed with Major PVL, Minor PVL or a Psychological Injury and for the 2 years following such diagnosis.

**PART 5: SETTLEMENT CLASS MEMBER'S DECLARATION**

**YOU ARE NOT ELIGIBLE TO RECEIVE ANY COMPENSATION UNLESS YOU SIGN THE FOLLOWING DECLARATION AND HAVE IT WITNESSED BEFORE YOUR MEDICAL DOCTOR.**

I solemnly declare that:

- 1. (a) I was implanted with a Silzone® Product; or  
 (b) I am a family member, heir or executor of the estate of a person who was a resident of British Columbia at the date of his/her death on \_\_\_\_\_ who was implanted with a Silzone® Product; and
- 2. My answers in Parts 1, 2 and 4 of this Claim Form are true and correct.

I make this solemn declaration conscientiously believing it to be true and knowing that it is of the same legal force and effect as if made under oath.

Declared before me at \_\_\_\_\_, this \_\_\_\_\_ day of \_\_\_\_\_, 2010.

\_\_\_\_\_  
Signature of Claimant

\_\_\_\_\_  
Medical Doctor's Signature

\_\_\_\_\_  
Doctor's Name and Address (print)

\_\_\_\_\_  
Telephone: \_\_\_\_\_

**IMPORTANT INSTRUCTIONS TO MEDICAL DOCTOR:**

**The Claimant must be present before you when you complete this form.**

**PART 6:                    DOCTOR'S DECLARATION**

I solemnly declare that:

1.     I am a physician licensed to practice in the Province of \_\_\_\_\_.
2.     The Medical Information referred to in Part 3 of the Claim Form which I have provided in support of the Settlement Class Member's Claim is true and correct.

I make this solemn declaration conscientiously believing it to be true and knowing that it is of the same legal force and effect as if made under oath.

Declared before me at \_\_\_\_\_, this \_\_\_\_\_ day of \_\_\_\_\_, 2010.

\_\_\_\_\_  
Medical Doctor's Signature

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Doctor's Name and Address (print)

\_\_\_\_\_  
Witness Name and Address (print)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Telephone: \_\_\_\_\_

Telephone: \_\_\_\_\_

**Once the Claim Form is completed, send it by post, facsimile or electronic mail by 4:00 p.m., June 30, 2010, to:**

Silzone® Product Settlement  
Poyner Baxter LLP  
408 –145 Chadwick Court  
North Vancouver, B.C. V7M 3K1  
Telephone: 604-988-6321  
Facsimile: 604-988-3632  
**Email: [info@poynerbaxter.com](mailto:info@poynerbaxter.com)**

**THE CLAIM FORM MUST BE RECEIVED BY POYNER BAXTER LLP BEFORE 4:00 P.M., JUNE 30, 2010. YOUR CLAIM WILL NOT BE CONSIDERED UNLESS IT IS RECEIVED BY POYNER BAXTER LLP BY 4:00 P.M. ON JUNE 30, 2010.**