

*For people with Bjork-Shiley Convexo-Concave (C-C)  
heart valves and their spouses...*

## **Your Benefits and Rights Under the BOWLING Settlement**

- What they are
- How to claim them

These instructions are to help you receive the benefits to which you are entitled under the Settlement as quickly and as easily as possible. Although you always have the right to seek advice from an attorney, this Settlement is designed to help you collect your benefits without calling on a lawyer.

Please follow the instructions on how to claim each benefit. The Claims Administrator will contact you as required to give you additional guidance so you can receive your benefits promptly.

If you have any questions, write to:

Claims Administrator  
P.O. Box 3598  
Cincinnati, OH 45201-3598, U.S.A.

*or call*

(800) 977-0779 in the U.S.A. or Canada  
00 (1) 513-421-3517 internationally.

Dear **Bowling Class Member**,

You are guaranteed benefits and rights under a Class Action Settlement designed to address certain valve-related needs of C-C valve recipients. This pamphlet explains the Agreement's benefits and tells you how to claim them.

As Special Masters assigned by the Court, we want to help you receive the benefits to which you are entitled as quickly and as easily as possible. Although you always have the right to seek advice from an attorney, this Settlement is designed to help you collect your benefits without calling on a lawyer.

Sincerely,

Hon. Robert L. Black, Jr.  
Peter J. Strauss, Esq.  
Special Masters/Trustees

**This pamphlet contains no medical information. For medical advice concerning your valve, consult your physician.**

## **The Class Settlement Agreement provides the four benefits below:**

### **Medical Consultation**

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### **Valve Replacement Surgery**

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- Payments are for the purpose of covering **the costs of talking to your doctor about your C-C valve**. But you may spend this money however you choose.

- Compensation for qualifying **valve replacement surgeries**.

- Research to develop **diagnostic techniques**—medical tests designed to identify the condition of your valve—and benefits that will help make such diagnostic techniques available to you. Currently, no such techniques have been accepted or approved for routine use.

- Guaranteed **compensation** in the event of valve failure due to **outlet strut fracture**. The payment will be made based on a guaranteed schedule of compensation.

*The benefits described in this pamphlet are for people who were alive with an implanted C-C valve on January 23, 1992, and their spouses on that date. See "Who is eligible for Settlement benefits?" on page 14 for details.*

*This pamphlet contains a summary of your benefits as a class member. Your actual benefits are as provided in the **Bowling Settlement Agreement**.*



# Medical Consultation

## Medical Consultation Benefits

A cash payment in an amount approved by the Court will be made to you and your spouse to pay for visits to your cardiologist or other health care provider to discuss your C-C valve. There is no restriction, however, on the use of this money, and you may spend it however you choose.

### *How much money will my spouse and I receive?*

You should receive at least \$3,000, and possibly more, and your spouse at least \$500 and possibly more, depending on how many people apply for medical consultation benefits.

### *How do I claim these medical consultation benefits?*

- 1) You must complete and file with the Claims Administrator a form entitled "Proof of Claim," together with the supporting information requested by the form, to prove that you were alive with an implanted C-C valve on January 23, 1992; and for spousal benefits, that you were married on that date.
- 2) You may have previously received a copy of this form in the mail. If you have already completed and returned the form, you need not do anything more unless the Claims Administrator contacts you for additional information. When your claim has been fully processed, your payment will be sent to you by check in one or more installments.
- 3) If you did not previously receive a copy of the "Proof of Claim" form, or if you did not return it and need another copy, please contact the Claims Administrator. ***The completed "Proof of Claim" form, along with the required proof, must be postmarked no later than March 31, 1996.*** (Please submit only one copy of this form.)



# Valve Replacement Surgery

## *Which valve replacement surgeries qualify for payment under the Settlement?*

A surgery to replace the valve due to the risk of outlet strut fracture qualifies for benefits under the settlement if the surgery complies with guidelines for C-C valve replacement set by a Supervisory Panel of experts appointed by the Court. The guidelines may be changed from time to time, so that a surgery that does not qualify when it takes place may qualify at a later date. It is suggested that you contact the Claims Administrator prior to your replacement surgery, if possible, to determine whether your surgery will qualify. In addition, a surgery that does not comply with the guidelines will be treated as complying if it is determined after the surgery that one leg of the outlet strut had separated from the flange prior to the surgery (a condition that some refer to as a "single leg fracture").

## **What are the benefits I will receive for my qualifying valve replacement surgery?**

The benefits for qualifying valve replacement surgeries are listed below:

- ***Payment of covered medical expenses not paid for by insurance or by government benefits.***

The Settlement will pay for the covered costs of your qualifying surgery that are not paid for by insurance and government benefits. **Proof of your actual expenses, such as a copy of the hospital and doctor bill, is required.**

- ***\$38,000 intended to pay for nonmedical expenses related to your surgery.***

Although this benefit is intended to pay for expenses such as home care during recuperation, you may spend this money however you choose. No proof of expenses is required.

- ***Reimbursement for actual lost income not paid by other disability benefits such as sick pay, disability insurance, or private or government programs.***

If you miss time from work due to your qualifying valve replacement surgery, you will be reimbursed for your lost income that is not covered by any other disability benefit options available to you, up to a maximum of \$1500 per week.

**Proof of lost income is required.** The Settlement requires medical proof of your inability to work if you claim more than 16 weeks of lost income.

- ***Extended disability or death compensation.***

If you have economic loss due to partial disability one year after the surgery, you will receive additional financial compensation. If the surgery results in your permanent total disability or death, you or your family will receive the benefits offered for outlet strut fracture compensation. (See page 12.)

Of course, the decision to undergo valve replacement surgery is entirely up to you and your physician. The Settlement does not in any way restrict or prevent anyone from having surgery to replace their C-C valve. The Settlement will only pay, however, for those valve replacement surgeries due to the risk of outlet strut fracture that comply with guidelines set by the Court-appointed Supervisory Panel or as otherwise specified in the Settlement.

# Valve Replacement Surgery

*continued...*

## *How do I claim benefits for my qualifying valve replacement surgery?*

- 1) To inquire whether or not your surgery qualifies for payment under the guidelines set by the Supervisory Panel, write or call the Claims Administrator at the address or phone number on the front and back covers of this brochure. The Claims Administrator will need your name, valve serial number, address, and telephone number. You may contact the Claims Administrator for information on payment before or after your surgery.
- 2) Following your surgery, if it is confirmed as qualifying, you will receive instructions on how to file proof of expenses. Also, if it is determined that one leg of your valve's outlet strut was separated from the flange prior to the surgery (a condition that some refer to as a "single leg fracture"), the Claims Administrator will refer you to Class Counsel for a consultation about your compensation options.
- 3) Once your claim is processed, you will receive reimbursement of covered medical expenses, and will be offered the additional benefits described on pages 6 and 7 for which you qualify.
- 4) You may elect to reject these additional valve replacement surgery benefits and instead bring an individual legal action against Shiley. However, if you choose to bring a lawsuit against Shiley, you will permanently lose your right to these additional valve replacement surgery benefits.
- 5) If you choose to accept these additional valve replacement surgery benefits, you will be required to sign a Court-approved form giving up any rights to bring legal action against Shiley. Once you have signed that form, and once your claim is fully processed, you will receive \$38,000 and the other additional valve replacement surgery benefits for which you qualify described on pages 6 and 7.



# Diagnostic Techniques

## Diagnostic Benefits

If diagnostic techniques to identify C-C valves at a significant risk of outlet strut fracture are accepted and approved by the appropriate regulatory agencies for routine use, the Settlement will provide benefits that will help to make such diagnostic techniques available to you. Such medical testing may provide you with information on the condition of your valve and assist you and your doctor in making a more informed decision about your medical care.

Currently, no such techniques have been accepted or approved.

## *How will I know if such techniques become available, and how will I claim those benefits?*

At this time, it is not possible to know if or when diagnostic techniques may become available. If such techniques do become available, the Special Masters/Trustees and Supervisory Panel will determine how to advise class members and how to provide Settlement benefits for diagnostic services.

*Joining the Patient Tracking System may make it easier to notify you. If you are not already a member of the Patient Tracking System and did not choose to join by checking the box on your "Proof of Claim" form, you may join by contacting the Claims Administrator.*

### **Outlet strut fracture benefits — what is the range of compensation?**

A substantial payment will be made to you or your family in the event that your valve experiences outlet strut fracture. You can receive this payment with no need to retain a lawyer and pay legal fees.

The exact compensation amount will be based on a Court-approved schedule of compensation that takes into account factors such as your family status, age, and income at the time of fracture.

## **Outlet Strut Fracture Compensation**

### **How do I claim outlet strut fracture benefits?**

- 1) If you have an outlet strut fracture claim, contact the Claims Administrator. Be sure to include the name and valve serial number of the person who had the fracture, your name, return address, and telephone number.
- 2) The Claims Administrator will review your claim and contact you as required to explain your rights and benefits and request additional information. The Claims Administrator will also explain to you that if you have an outlet strut fracture, you are entitled to select one of three options:
  - a) Compensation based on a Court-approved schedule (see box on page 12); or
  - b) Arbitration; or
  - c) Individual legal action.
- 3) If you choose to accept the compensation based on a Court-approved schedule, you will be required to sign a Court-approved form giving up any rights to bring legal action against Shiley.
- 4) If you choose to arbitrate or to bring a lawsuit against Shiley, you will permanently lose your right to the outlet strut fracture compensation based on the Court-approved schedule.



## Miscellaneous Questions

### Who is eligible for Settlement benefits?

A person is entitled to the benefits of the Settlement if he or she was alive with an implanted C-C heart valve\* on January 23, 1992, or was such person's spouse on that date, and did not ask to be excluded from the Settlement.

### How do I know if I have a C-C valve?

You have a C-C heart valve\* only if your valve serial number has a "C" in it. You can find your valve serial number on the implant data card that you may have received after your surgery.

If you do not have an implant data card, contact your doctor or the hospital where your valve was implanted. They may be able to help you identify the type of valve you have. For further information, in the United States and

Canada, call Medic Alert at (800) 245-1492 (if you are enrolled in the U.S. patient registry) or Shiley at (800) 626-3363; outside the United States and Canada, call Shiley at 00 (1) 714-863-5454.

\* This Settlement provides benefits *only* to people who were alive on January 23, 1992, with an implanted Shiley C-C heart valve, and their spouses on that date. This Settlement does not apply to people implanted with a non-Shiley valve or with *any other* Shiley heart valve. For example, this Settlement does *not* apply to people with the Shiley Radiopaque Spherical (R-S) or Monostrut heart valves.

### What is the purpose of the Patient Tracking System and how do I enroll?

A confidential Patient Tracking System, which is free of charge to people with C-C valves, has been established to keep you informed, through your physician where appropriate, of any new and significant medical information regarding your valve.

People with C-C valves are encouraged to enroll in the Patient Tracking System. If you are not already a member of the Patient Tracking System and did not choose to join by checking the box on your medical consultation claim form, you may join by contacting the Claims Administrator. For more information on the Patient Tracking System, you may call one of the same telephone numbers for your area listed on page 14 as providing valve identification information.

### To receive a copy of the Settlement Agreement...

These instructions are to guide you in claiming your benefits but do not describe every term of the Settlement. The Settlement defines your rights and obligations. For a copy of the Settlement, contact the Claims Administrator. You may contact Class Counsel by writing to Stanley Chesley, 1513 Central Trust Tower, Cincinnati, Ohio 45202, U.S.A. or calling 00 (1) 513-621-0267.



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