

Patient Guide



For Class Members
in the
Bowling-Pfizer Litigation

2003 Amended Guidelines
for Determining Eligibility
for Monetary Benefits
for Elective Explantation

Bjork-Shiley
Convexo-Concave
Heart Valve Recipients

As you already know...

Between 1979 and 1986, thousands of people worldwide had one or more of their natural heart valves replaced with a BSCC heart valve.

The BSCC heart valve has a tilting disk, which is held in place by an inlet strut and an outlet strut. The outlet strut can fracture and the disk can break free. This event is known as OSF. For most patients, the risk of OSF is extremely low. Although rare, OSF could cause death or serious permanent injury.

In some cases, a patient can undergo an operation (called explantation) to replace the valve.

Some patients who undergo elective explantation due to the risk of strut fracture are eligible for monetary benefits. If a patient, with the advice of a doctor, decides to undergo explantation, he or she may be entitled to monetary benefits under the Guidelines.



Why Guidelines?

The 2003 Guidelines, like earlier versions, were developed under the Bowling-Pfizer settlement **to determine who is eligible for monetary benefits** for elective surgery to replace a BSCC heart valve. These guidelines are not intended to constitute medical advice to patients with BSCC heart valves. Medical decisions are to be made by patients and their physicians.

Monetary benefits—which are available to people who fit certain criteria—are specific:

- payment of covered medical expenses not paid for by insurance or by government benefits
- lump sum payment of \$38,000 to pay for non-medical expenses related to the surgery
- reimbursement for actual lost income not paid by other disability benefits (with limitations)
- extended disability or death compensation

Eligibility for monetary benefits for elective BSCC valve replacement surgery is based on the Supervisory Panel's improved formula to calculate estimated annual rates of OSF.



What's new about the 2003 Guidelines?

The 2003 Guidelines include **a new risk factor for calculating estimated annual strut fracture rates**. This new risk factor is **manufacturing rework status**. "Rework" refers to any special step taken during the manufacturing process, such as re-welding the outlet strut or polishing the strut to remove cracks that appeared after welding. Rework is associated with an increased risk of fracture.

For the vast majority of patients, these Guidelines will not affect their medical care.

How is eligibility for monetary benefits determined under the 2003 Guidelines?

Two values are compared:

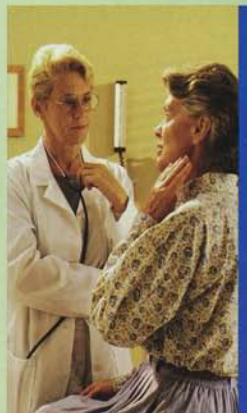
1. risk of valve fracture
2. risk of surgery to replace the valve

How are risk of strut fracture and risk of surgery determined?

The **risk of outlet strut fracture** is based on several risk factors:

- patient's age
- patient's gender
- valve size
- position of the implant (mitral and/or aortic)
- several manufacturing characteristics, including rework status, the welder group, and the date of manufacture

A statistical analysis is used to calculate the probability that the valve will fracture.



Please note: The calculation that a valve will fracture is based on statistical averages of group data. The risk to an individual may differ. Most people will never experience a strut fracture. For example, there have been no reported outlet strut fractures of any 60° BSCC heart valve manufactured after April 1, 1984.

The **risk of surgery** refers to the risk that a patient will become sicker or die from an operation to replace the BSCC heart valve. The calculation of risk is based on heart valve explant data and is affected by a patient's age and the number of valves being replaced.

To determine your estimated risk of OSF, you or your physician should provide the Claims Administrator with the valve serial number, your age, your gender, and valve implant position.