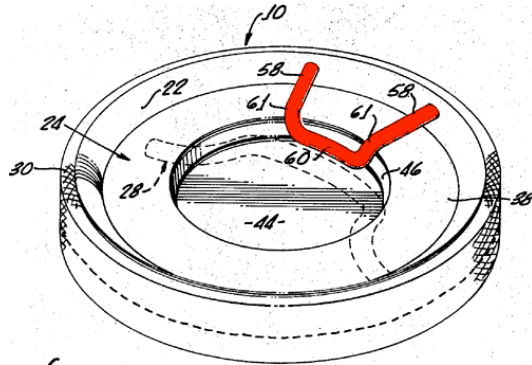


The Bjork-Shiley Heart Valve

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The Bjork-Shiley Heart Valve was used to replace damaged aortic and mitral valves in the heart. Upon its introduction in 1971 it marked the first successful titling disk heart valve. It was originally manufactured by Shiley and later by Pfizer after they bought out the Shiley Company.

This particular model is constructed from a single carbon-coated disk held in place by a metal housing. The metal housing is circular with a beveled edge. On the edge of the housing are an inflow and an outflow strut. These struts are used to hold the disk in place during the hearts systolic and diastolic contractions. This standard design is durable and was widely used in the 1970s. This design was referred to as the Convexo-Concave Valve.



The failure of the Convexo-Concave Valve design was brought about when attempted improvements to design and increasing manufacturing speed were put into action. Beginning in 1979 valves with the improved Convexo-Concave design fractured at the outflow strut. Fractures occurred on the strut at the point where it was welded to the metal housing. One side of the strut would fracture followed by the other end a few months later. These fractures resulted in valve failure and death due to cardiac arrest.

Approximately 619 cases of the 80,000 valves implanted fractured resulting in over

350 deaths. It also became apparent that valves welded by specific workers were at higher risk of fracture than those welded by other workers.

By 1986 the convexo-concave valve was forced off the market by the FDA. Even though the FDA forced the recall of this particular valve model not all the implanted valves were removed and replaced. The reason not all of the implanted valves were not replaced is that certain other risks may have outweighed the risk of the strut fracture.

Some of the other risks are surgery, age, size, and location (either mitral or aortic valves) all factored into the decision of whether or not the replacement was worthwhile. Also a compensation fund was established to provide money for patients and cost of heart surgery to replace valves

This recall is referred to as one of the most infamous recall cases of all time. It comes down to some basic ethical issues and over sights. Some of the problems that can be seen are sacrifice of quality to improve manufacturing speed, which proved to be a catastrophic and fatal decision impacting several innocent individuals. The inadequate performance of welders also proved to be quite instrumental in the failure of these valves.

There may have been a lack of interest in quality assurance testing that could have also prevented these problems.

References:

www.fda.gov
<http://www.healthdangers.com/medical-devices/bjork-shiley/index.htm>
http://en.wikipedia.org/wiki/Bjork-Shiley_valve