St. Jude Medical’s mechanical heart valve is still the market standard 25 years after a Minnesota woman received the first implant in surgery at the U of M.

By Terry Fiedler
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Manny Villafana founded St. Jude Medical Inc. as a heart-valve manufacturer and now competes against it. He knows just how formidable St. Jude’s mechanical valve has been.
"If you’re competing against Oreo cookies, you better have a good cookie," said Villafana, chairman of ATS Medical Inc. in Plymouth.

Twenty-five years to the day after it was implanted for the first time, St. Jude’s mechanical heart valve remains the leading product in its category, a feat virtually unmatched in an industry not known for long product shelf lives.

About the only medical product that has remained the standard for a longer period is the Band-Aid, quipped A.G. Edwards analyst Jan David Wald.

Worldwide, more than 1.3 million valves have been implanted, and the device still accounts for 85 percent of the U.S. mechanical heart valve market and 50 percent of the world market.

Last year, sales of St. Jude’s mechanical valves totaled more than $200 million - at about $5,000 a pop - and the valves provided a hefty 40 percent net profit margin.

They’re no longer the
Worldwide, more than 1.3 million St. Jude mechanical heart valves have been implanted, and the device still accounts for 85 percent of the U.S. market.

Dr. Demetre Nicoloff designed the bi-leaflet valve on which St. Jude was founded, according to Manny Villafana, the company’s founder.

Helen Heikkinen of Angora, Minn., was the recipient of the first St. Jude valve. She died in 1988, 11 years after the life-saving implant, of renal failure.

ST. JUDE from D1

Only ‘minor modifications’ to basic design, materials

biggest-selling product at Little Canada-based St. Jude, which also makes pacemakers and defibrillators, but the valves laid the foundation for what has become a $1.3 billion company that employs about 1,800 people in Minnesota and 6,000 overall.

Dr. Robert Emery, who participated in the first implant of the valve and is a consultant to St. Jude, said that while some “minor modifications” have been made, the basic design and materials remain the same in the current valves as those in 1977.

“Some instruments have stayed around that long,” Emery said, “but nothing as technologically complex as this - nothing in cardiovascular.”

Many attempts

The heart’s natural valves normally keep blood flowing forward through the heart. Congenital defects or disease can cause the valves to malfunction, so they don’t pump enough blood or allow blood to backflow. In time, the overworked heart begins to fail, causing shortness or breath, dizziness, chest pain, fatigue or fluid retention.

Over the years, there were many attempts at finding a suitable replacement valve. In the 1960s, the University of Minnesota’s Dr. C. Walton Lillehei, regarded as the “father of open-heart surgery” and

Dr. Bhagavant Kalke, a surgical fellow, collaborated on a design based on irrigation dams in Kalke’s native India.

The new bi-leaflet mechanical heart valve opened to allow blood to flow through, then immediately closed to keep blood from backing up.

Although Lillehei is widely credited with the design of St. Jude’s mechanical valve, Villafana said the bi-leaflet valve on which he founded the company was very different and designed from the ground up largely by the University of Minnesota’s Dr. Demetre Nicoloff and an early St. Jude employee, Don Hanson.

Villafana, who had successfully built and sold a company called Cardiac Pacemakers Inc. before starting St. Jude in 1976, said it was Nicoloff and bioengineer Chris Possis who first brought the idea for a new bi-leaflet valve to him.

“I knew nothing about valves,” Villafana said. “I came from the electrical side [pace-makers], but doctors had told me my next project should be a heart valve, because a better one was needed.”

The new St. Jude valve was better. It was made of different materials - graphite coated with pyrolytic carbon, which is so hard that blood was less likely to stick to it. Its design also minimized clotting, so patients could dial back on blood-thinning drugs; and it was easier to implant than other devices and quieter, too.

First implant

On Oct. 3, 1977, in a surgery at the University of Minnesota, Nicoloff implanted the first St. Jude Medical heart valve into Helen Heikkinen of Angora, Minn.

The university had been the scene of many huge medical firsts, including the first open-heart surgery years before. Emery, a resident in the same lab as Nicoloff, said he knew even then the valve was also “a big deal.”

“It took awhile to prove itself, but by the early 80s it was regarded as a giant step forward in valve-replacement surgery,” he said.

Over the years, St. Jude built on a track record of reliability as competitors struggled, said U.S. Bancorp Piper Jaffray analyst Thomas Gunderson.

The valve also was aimed at a market that put a lot of stock in track record and reliability.

“Cardiac surgeons are conservative by nature,” said analyst Wald. In contrast, “interventional cardiologists will try anything that comes out.”

The long-standing relationship with doctors was tested in 2000 when St. Jude recalled some of its unimplanted inventory and monitored 36,000 patients for possible higher incidents of heart-valve leakage. The higher probability of leakage, which the company discovered and reported, was due to a silver coating put on the valve to prevent infection.

One analyst said at the time the company tripped while trying to “gild the lily.”

But the recall essentially had no effect on the loyalty that customers showed to the product.

The mechanical valve now is losing some customers because of the increasing popularity of tissue heart valves from pigs or cows, which don’t last as long but don’t require patients to take the blood-thinning drugs required with mechanical valves.

Tissue valves now account for 42 percent of the U.S. market valve market vs. 37 percent for mechanical valves, according to Gunderson.

Even so, the St. Jude valve remains the most popular single product, either mechanical or tissue.

Gunderson says that makes sense.

“After 25 years, there’s an attitude, ‘If it ain’t broke, don’t fix it.’”

“I knew nothing about valves....But doctors had told me my next project should be a heart valve, because a better one was needed.”

–Manny Villafana, founder, St. Jude Medical

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