MEDICAL TECHNOLOGY

HEARTENING DEVELOPMENTS FOR ST. JUDE'S RIVALS

Firing distributors and skimping on R&D could cost it plenty

CEO LEHMKUHL: "20 YEARS FROM NOW . . . SURGEONS WILL STILL BE USING THE ST. JUDE VALVE"

It has been a charmed half-decade for St. Jude Medical Inc. The St. Paul (Minn.) maker of the world's most popular heart valve soared to the top of its lucrative market after two of its toughest rivals—Baxter International Inc. and Pfizer Inc.—stopped selling their designs because of celebrated product failures. That let St. Jude raise prices up to 10% annually without investing a dime to change its 14-year-old design. Last year, its profits surged 24%, and its stock has jumped 78% in 17 months, to 43, or 24.5 times earnings.

But St. Jude's success is attracting a rush of entrants into the $400 million heart valve market. And a series of questionable moves—such as firing its European distributors and relying too much on a single product—is leaving St. Jude vulnerable. Carbomedics Inc., the industry's main supplier of a clot-resistant carbon coating for valves, is selling a St. Jude clone in Europe. Manuel A. Villafaña, St. Jude's flamboyant founder and former chairman, has just reunited the team that designed St. Jude's leading product. His company, Helix Biocore Inc., plans to begin implanting its new valve in humans in Europe by yearend. And Baxter and Medtronic Inc. are racing to perfect their valves. "No one has built the perfect heart valve yet," says Dennis Sellke, who heads up Medtronic's valve division.

SMOOTH FLOW. With Villafaña at the helm, St. Jude came close in 1976. Valves are the gatekeepers of the heart. The right and left sides of the organ are each divided into chambers: The upper chamber is the atrium, where the blood comes in. The lower is the ventricle, where it's pumped out. Two valves control the openings between the atrium and the ventricle of each side of the heart. Two more valves control the passageways from the ventricles into the vessels that carry blood away from the heart. Each valve prevents backflow so that blood moves only in one direction.

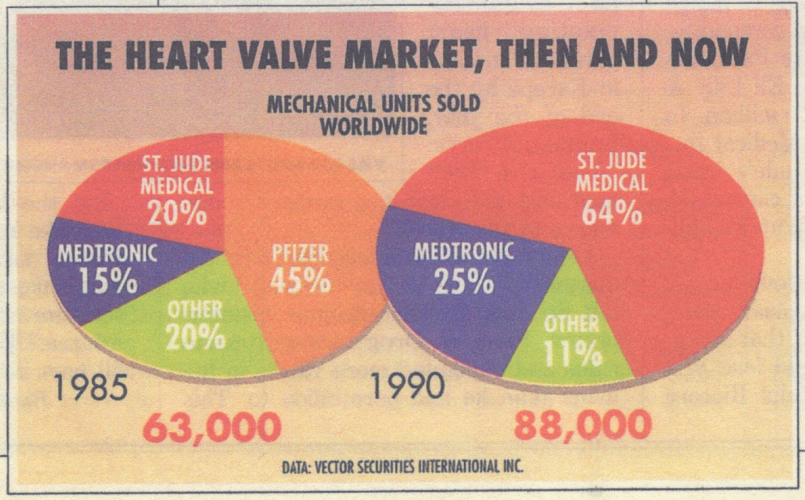
Prosthetic heart valves are needed when natural ones fail to adequately regulate the flow of blood. Diseased valves may not close completely or may be constricted. People with failing heart valves may suffer from fatigue, chest pain, and dizziness. The problem is most often the result of aging.

About 33% of replacement heart valves are taken from animals and cadavers. But they often don't last more than five years. So mechanical valves have been gaining market share and are expected to account for 80% of the total valve market by 1995. And after more than 320,000 implants worldwide, only 3% of St. Jude's valves have been implicated in clotting that could cause strokes, one of the lowest clotting rates in the industry. One reason is its elegant design, which lets blood flow smoothly through the valve. "Twenty years from now, a large percentage of surgeons will still be using the St. Jude valve," declares CEO Lawrence A. Lehmkuhl.

So far, his competitors have been jinxed. Pfizer's Bjork-Shiley valve was recalled in 1986 after key support struts fractured. Baxter withdrew its Duromedics/Hemex valve in 1988, when the carbon-coated "doors" of the valve began eroding. Since then, surgeons and regulators in the U. S. have become wary of new valves. "It's hard to get new valves accepted because we've seen so many fail," says John A. Macoviak, a Boston heart surgeon.

Still, St. Jude's rivals are undeterred. And St. Jude may inadvertently be helping them advance. The distributors it cut off in six European countries helped account for 55% of its total unit sales and 32% of its revenues. St. Jude hopes to boost profits by selling direct and capturing the 10% net operating margin that distributors earned. In Europe, where there is more competition and fewer regulatory hurdles, heart valves cost about $3,000, vs. $3,800 in the U. S. In the quarter ended Mar. 31, St. Jude's sales rose 14.6%, to $52.3 million, and profits jumped 21%, to $20.2 million. But Barbara L. Santry, an analyst at Dain Bosworth Inc. in Minneapolis, says unit volume dropped 18% on the Continent as St. Jude's market share fell three points, to 30%. Since then, its shares are off about 15%.

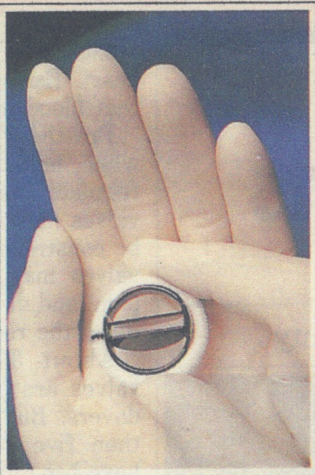
One disaffected custom-



PHOTOGRAPH BY LAYNE KENNEDY; CHART BY ALBERTO MENA/BW

er is Dr. Axel Haverich, a cardiac surgeon from Hanover, Germany, who buys valves for his 1,150-bed hospital. He has quit buying St. Jude valves because of concerns about service since his distributor was dismissed. "That's a surgeon we haven't had a chance to sit down with," says Lehmkuhl.

'HIGH-HANDED.' Meanwhile, St. Jude's rivals are on the march. Last July, Baxter relaunched an improved version of the valve it had withdrawn in nearly every market except the U. S., where it is still awaiting FDA approval. Another beneficiary is Carbomedics, which last year agreed to pay a licensing fee to St. Jude for a knockoff valve the company has sold for three years in Europe. "They've been high-handed with their distributors and surgeons because they felt they were in a superior position," says Frank L. Tamru, Carbomedics' director of sales and marketing for Asia and the Pacific.



ELEGANT DESIGN: ST. JUDE'S VALVE PREVENTS CLOTS

Lehmkuhl says "we did not mistreat our distributors." He says he gave notice well in advance of cutting them off. Still, Dain Bosworth's Santry believes that Carbomedics is picking up St. Jude's lost market share.

That's good news for the Austin (Tex.) company, which has a beef with Lehmkuhl. Until recently, St. Jude was Carbomedics' biggest customer for carbon coating, buying about $35 million worth a year. But on May 6, the FDA gave St. Jude approval to use its own coating in valves sold in the U. S. Now, Carbomedics is cheering on St. Jude's rivals, who are also potential customers for its coating. It is licensing its own valve design to Villafaña and sharing the costs to develop it. And it will sell its coating to Helix. Villafaña claims his old team of specialists has a valve that will produce less clotting than St. Jude's. He also says that the Helix valve can be X-rayed—therefore monitored noninvasively—and is easier to implant. Villafaña has even signed on Richard W. Kramp, former head of sales and marketing who got St. Jude rolling in 1978.

Villafaña's trump card may be his financial backers: several of St. Jude's former European distributors. Flush with cash yet without a valve to offer, they put up $5 million in a private placement in January to back Villafaña, a native of New York's South Bronx whose parents came from Puerto Rico in the 1920s.

One thing is sure: St. Jude, which depends on its heart valve for 94% of its revenues, can't afford to take any challenge lightly. It has a hefty cash trove and little debt, but has failed to diversify. Moreover, the patent on its valve expires in 1998. FDA approval takes at least five years. So St. Jude is working on a next-generation valve that it hopes will reduce clot formation and the need for anticoagulants. To achieve this, Lehmkuhl plans to bump up R&D spending from 3.6% of sales to 6%, the industry average. Time will tell if that's enough to keep his competitors at bay.

By Julia Flynn Siler in St. Paul, Minn.

CAN THE MAN WHO BUILT A BETTER HEART VALVE DO IT AGAIN?

Manuel A. Villafaña is a bit of a departure from your usual medical entrepreneur. Forget lab coats or advanced degrees. Villafaña, who prefers flashy suits and cuff links shaped like heart valves, earned his top diploma from Cardinal Hayes High School in the South Bronx. Ask about the diamond ring on his right hand, and he'll tell you he designed the setting for the 2.02-carat, investment-grade gem. "You could buy a house with this diamond," he adds. His Rolls-Royce and '47 Cadillac? "We like to have fun," he explains.

But don't let appearances fool you. Villafaña, who is known as Manny in the industry, boasts a busy if mixed track record at starting up companies. In 1972, he founded Cardiac Pacemakers Inc., which was sold to Eli Lilly & Co. six years later for $127 million. In 1976, he founded St. Jude Medical Inc. In 1981, after seeing St. Jude's heart valve through four years of clinical trials in Europe, Villafaña left under still-disputed circumstances.

Two years later, he co-founded GV Medical Inc., a laser-angioplasty company. In 1987, Villafaña left that struggling company, which would lose $7.9 million in 1990, to start Helix Biocore Inc. Helix planned to offer cell-growing services to drug and biotech companies but eventually turned to the heart-valve market when cash grew tight.

'BEAUTIFUL.' This latest venture is a touchy subject with St. Jude CEO Lawrence A. Lehmkuhl, who calls Villafaña's efforts at a comeback "nothing but hype." He groups Villafaña with "the 30 others trying to develop mechanical valves. We'll be ready for him." As for Villafaña's claim that he'll begin implanting heart valves in humans in Europe by the end of the year, Lehmkuhl says: "You can take anything and stick it in humans somewhere in the world."

VILLAFANA: FLASH AND SALESMANSHIP

Lehmkuhl, a former accountant, dismisses Villafaña as "a salesman" who left St. Jude because he had misinterpreted Food & Drug Administration rules and implanted more valves in humans than he had permission to. This crisis, Lehmkuhl asserts, nearly led to the company's shutdown. Villafaña calls the charge "totally incorrect" and says the board "begged" him to stay.

Whatever the case, Villafaña does seem a gifted salesman. At a recent convention of heart surgeons in Washington, he was pitching his new valve to Walter Vancampenhoudt, St. Jude's former distributor in Belgium. After his presentation, complete with a prototype of the valve and photos, Villafaña had a believer. "It's beautiful," Vancampenhoudt declares. "There's no doubt about its success."

But the key is what doctors think. "We take manufacturers with a grain of salt," says Carl Backer, a Chicago heart surgeon. "We read the scientific literature and know from our own experience." Ultimately, Villafaña's valve will have to meet that difficult test.

By Julia Flynn Siler in Chicago

PHOTOGRAPHS BY LAYNE KENNEDY