



*THE PENN STATE
HEART-ASSIST PUMP*

*INTERNATIONAL HISTORIC
MECHANICAL ENGINEERING
LANDMARK
SUSQUEHANNA SECTION*

*UNIVERSITY HOSPITAL
THE MILTON S. HERSHEY MEDICAL CENTER
HERSHEY, PENNSYLVANIA
MAY 19, 1990
PENNSTATE*





The Penn State Heart-Assist Pump, developed through an interdisciplinary effort of the Colleges of Medicine and Engineering, is the first smooth, surgically implantable, seam free, pulsatile blood pump to receive widespread clinical use.

INTRODUCTION . One to 5 percent of open-heart surgery patients cannot be weaned from the heart-lung machine. Prior to development of successful heart-assist pumps, these patients died. The pumps also benefit candidates for heart transplants whose hearts are not strong enough to sustain them until a suitable donor is found. A heart-assist pump can sustain these patients for weeks or months. A successful heart-assist pump could save an estimated fifteen thousand individuals annually.

The Penn State heart-assist pump has provided circulatory support for more than fifty-five patients at Penn State's Milton S. Hershey Medical Center and more than two hundred patients worldwide. Thirty-five percent of those patients, who could not otherwise be weaned from cardiopulmonary bypass, survived because of the heart-assist pump. When used as a bridge to transplant, the pump has a success rate greater than 90 percent, saving many patients who would die without the pump. There has never been a device-failure-related fatality of any of these patients. The Penn State heart-assist pump pioneered design and operating principles that now are applied to all current blood-pump designs.

HISTORY OF THE PENN STATE HEART-ASSIST PUMP. In 1970, William S. Pierce, M.D. (a chemical engineer and surgeon), joined Penn State's Milton S. Hershey Medical Center. Dr. Pierce's interest in heart-assist pumps and artificial hearts had begun in the early 1960s; when he arrived at Penn State, he immediately initiated a collaborative effort in this area between the Colleges of Medicine and Engineering. The initial collaboration consisted of Dr. Pierce in the College of Medicine, and in the College of Engineering, Dr. John Brighton, a mechanical engineer, Dr. Winfred Phillips, an engineer, and Dr. Gerson Rosenberg, then a mechanical engineering graduate student. Later, Dr. David Geselowitz headed the team in the College of Engineering. A team of fabrication specialists and machinists headed by James Donachy, as well as veterinarians and animal care technicians, assembled in Hershey. Other members of this engineering team included faculty and graduate students from mechanical, aerospace, and chemical engineering and materials science.

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The development of the Penn State heart progressed through several stages over a period of years. During the early 1970s, the group developed a sac-type artificial heart and heart-assist pump. In this sac-type device, the pump was effective but the air pressure created by forcing air between the sac and the rigid case could cause the sides of the sac to touch. This touching and mechanical rubbing theoretically could cause excessive blood damage. Flow-visualization studies of the ball-type valve used in this device showed that the valves created a stagnation region in the apex.

Dr. Pierce and Mr. Donachy received U.S. patent #4,222,127 on September 16, 1980, but there was significant input from many members of the research group.

The next prototype device was similar to the current Penn State heart-assist pump in that a portion of the sac was tethered or fixed to the case. This ensured that the blood-pump sac walls could not touch and thus reduced blood damage. Problems with bonding of the blood sac and delamination of the tethering site, along with clot formation in the bond region, led to discontinuation of this model.

A third device used a separate diaphragm, fixed in the equatorial plane in the transverse section. This design imposed extreme stresses on the blood sac in the flexing region, causing early sac and diaphragm failures.

The current heart-assist pump uses the diaphragm and tethering features. Fluid dynamic studies indicated that a tilting disc valve was a more suitable option than a ball valve for the device. The studies also led to a reorientation of the inlet port that provided improved flow patterns.

Dr. Pierce and Mr. Donachy received U.S. patent #4,222,127 on September 16, 1980, but there was significant input from many members of the research group. Drs. Brighton and Phillips's contribution dealt with flow phenomena and pump shape. Dr. Rosenberg's contributions were in the area of mechanical design and pump bench evaluation. Testing began in 1973, with FDA approval in 1980. By 1984, the Penn State heart-assist pump was in widespread use.

DESIGN OF THE PENN STATE HEART-ASSIST PUMP. The Penn State heart-assist pump is the first extremely smooth, seam free, pulsatile blood pump to receive widespread clinical use with excellent results. The pump pioneered the application of fluid-mechanics principles in blood-pump development and the use of segmented polyurethane as the blood-contacting material. An interdisciplinary group including surgeons, engineers, materials scientists, veterinarians, and fabrication specialists designed the pump using fundamental engineering principles and problem-solving techniques.

Designing and manufacturing a device with an extremely smooth, seam free inner surface was crucial to the pump's success. Formed elements in blood, such as platelets and red and white blood cells, can lodge and attach in seam or crease areas. An extremely smooth surface is necessary because any defect larger than formed blood elements is a potential site for clot formation. To form the extremely smooth inner surface of the blood sac, a hollow wax form shaped like the blood sac is created by a dip or rotational-molding process. The wax form is polished and then coated with filler-free silicone rubber. The silicone rubber provides an extremely smooth, high-gloss surface on the epolene wax form.

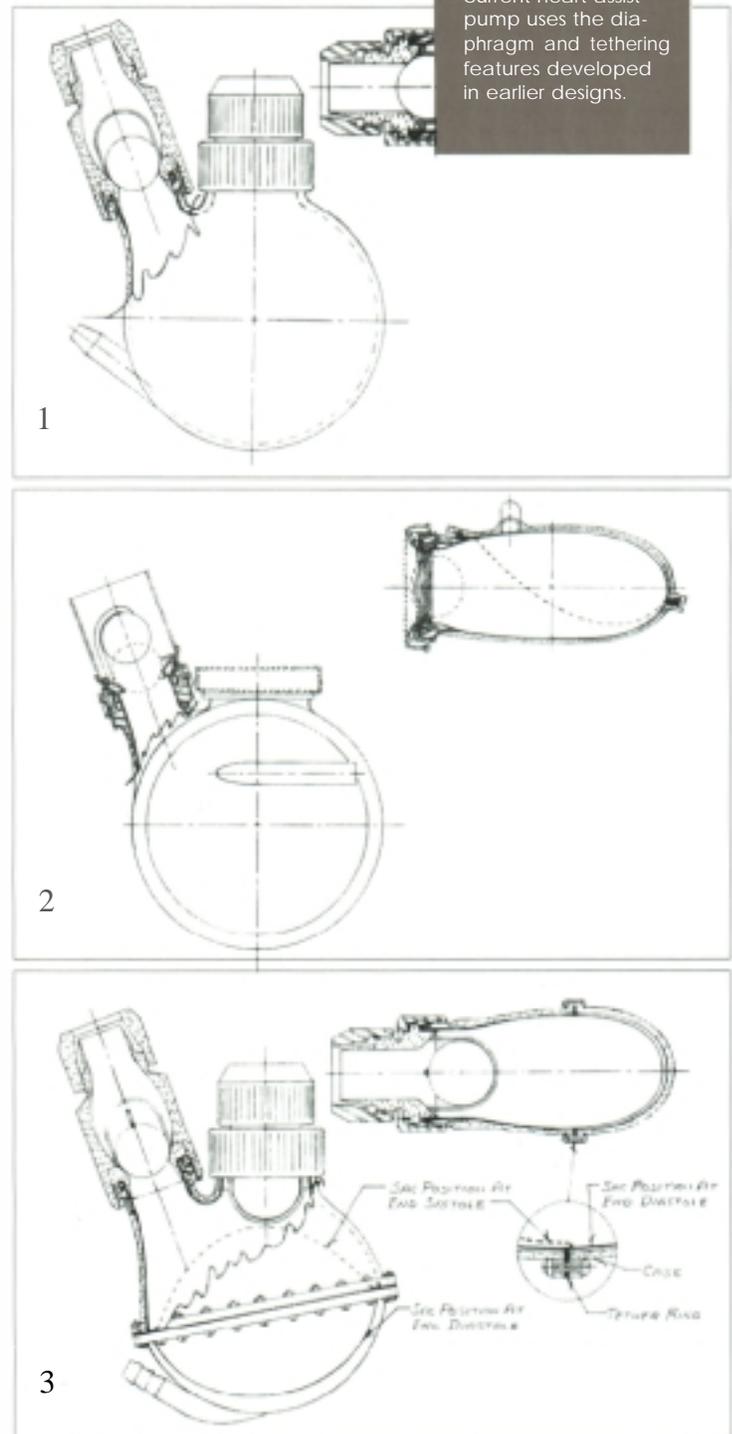
Polyurethane dips of the form are repeated to obtain the desired sac thickness. After the polymer has dried, the wax and silicon rubber coating are melted and mechanically removed. Heat setting the polyurethane sac allows further shaping and contouring.

Determining the specific geometry that would allow for easy fabrication and anatomical fit, as well as producing minimal mechanical stresses on the pumping membrane and satisfactory blood flow patterns within the pump, required several

1. In the earliest prototype left-ventricular-assist pumps, the sac-type blood pumps could damage the blood if over driven.

2. The second-generation sac-type blood pump employed a tether ring, effectively converting it to a diaphragm-type pump.

3. The third blood pump used a transverse tether design with a separate diaphragm. The current heart-assist pump uses the diaphragm and tethering features developed in earlier designs.



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years. Anatomical considerations determined the pump's general shape. Fluid-mechanics studies determined regions of stasis or high shear stress.

Elimination of regions of stasis was important because areas where blood can sit are areas where clots will form. Regions of high shear stress can destroy formed blood elements or can damage them sufficiently to activate the clotting system.

These fluid-mechanics studies initially used tracer particles within the fluid, evaluating flow patterns using still photography and high-speed video analysis. Analysis of fluid dynamics within the pump also included pulse Doppler ultrasound, hot-film anemometry, and three-component laser Doppler anemometry. These fluid-mechanics studies helped define the proper type of heart valve—tilting disc or central occluder—along with proper valve orientation. Today, these same fluid-mechanics studies continue on blood pumps under development at Penn State.

Early in the pump's development stage, analog computers simulated the device's pumping action. Later, in the mid-1970s digital computer simulations examined the pump's characteristics.

A mock circulatory system was used to run endurance and performance bench tests on the heart-assist device. Mock circulatory systems are mechanical systems that simulate the body's hydraulic impedance, allowing testing of devices under physiologic load. Dr. Rosenberg developed the mock circulatory system at Penn State in 1972.

The devices were tested for at least twice the intended period of use, typically bench tests of two months. Extensive animal testing also was carried out. The devices were implanted in Holstein calves and run for up to nine months. All device testing was performed as required by the U.S. Food and Drug Administration.

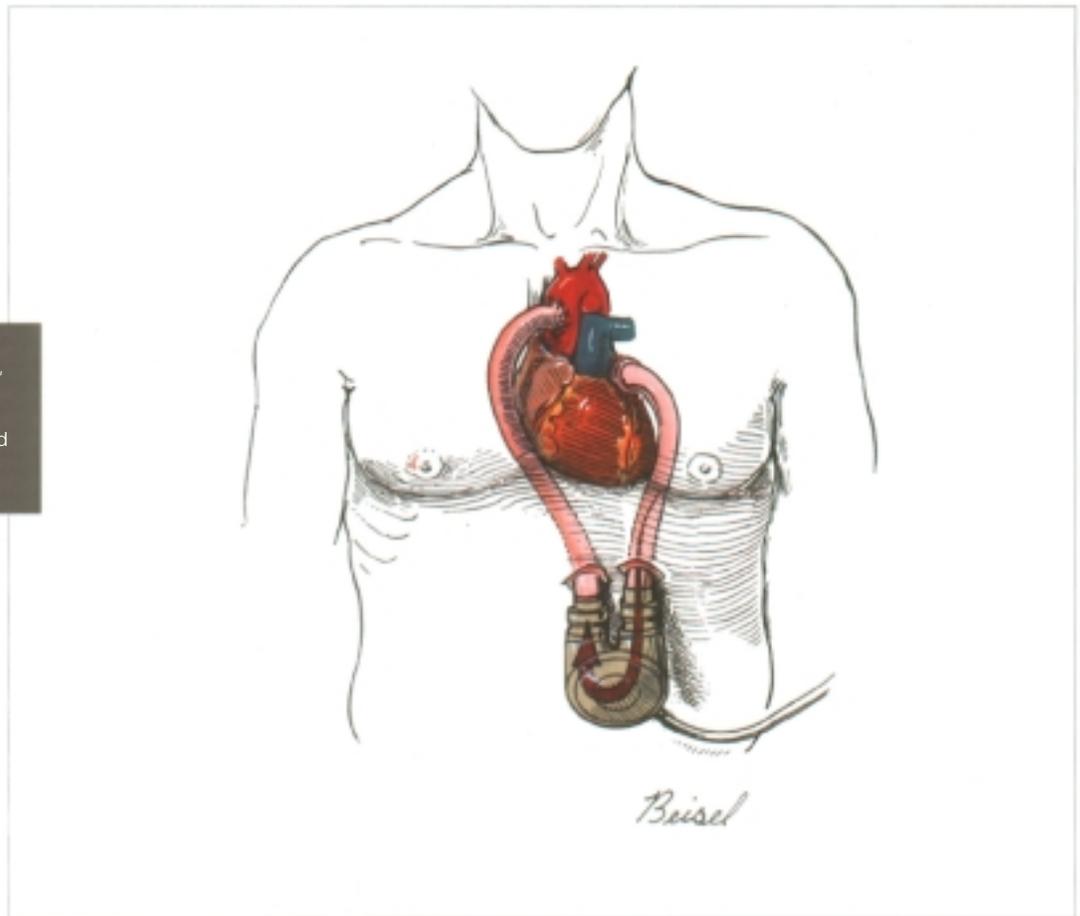
Device failures occurred rarely. Those failures that did occur were fatigue failures of the blood sac caused by excessive stresses. Blood sac redesign has greatly reduced this problem. Wear of heart valves or other components has not been a problem.

The only static stress failure of devices occurred when calves put their full weight on the device against a bar, causing some cracked cases. Cases are now made of a thicker, stronger material.

USE OF THE PENN STATE HEART ASSIST PUMP. The heart-assist pump attaches to either the left or right side of the patient's heart and assists either the left or right pumping chamber. If necessary, two pumps can assist both the left and right sides of the patient's heart simultaneously. The most typical use of the pump is on the left side, the chamber that most often needs assistance. The heart-assist device pumps blood from the left atrium, which is the filling chamber for the left side of the heart, through the heart-assist pump and returns it to the aorta, the main blood vessel leaving the heart.

Blood enters the pump from the left atrium at a pressure of less than 20 mm Hg (0.4 psig) and is then pumped into the aorta at an average mean pressure of 100 mm Hg (2.0 psig). For an average-size human, the blood pump will pump approximately five liters (1.3 gallons) of blood per minute. The tubes attaching the blood pump to the patient's heart pass through the skin of the patient's abdomen, where the blood pump sits. An air-drive line, which provides the pneumatic power source for the pump, attaches externally to the blood pump and runs to the pneumatic drive unit.

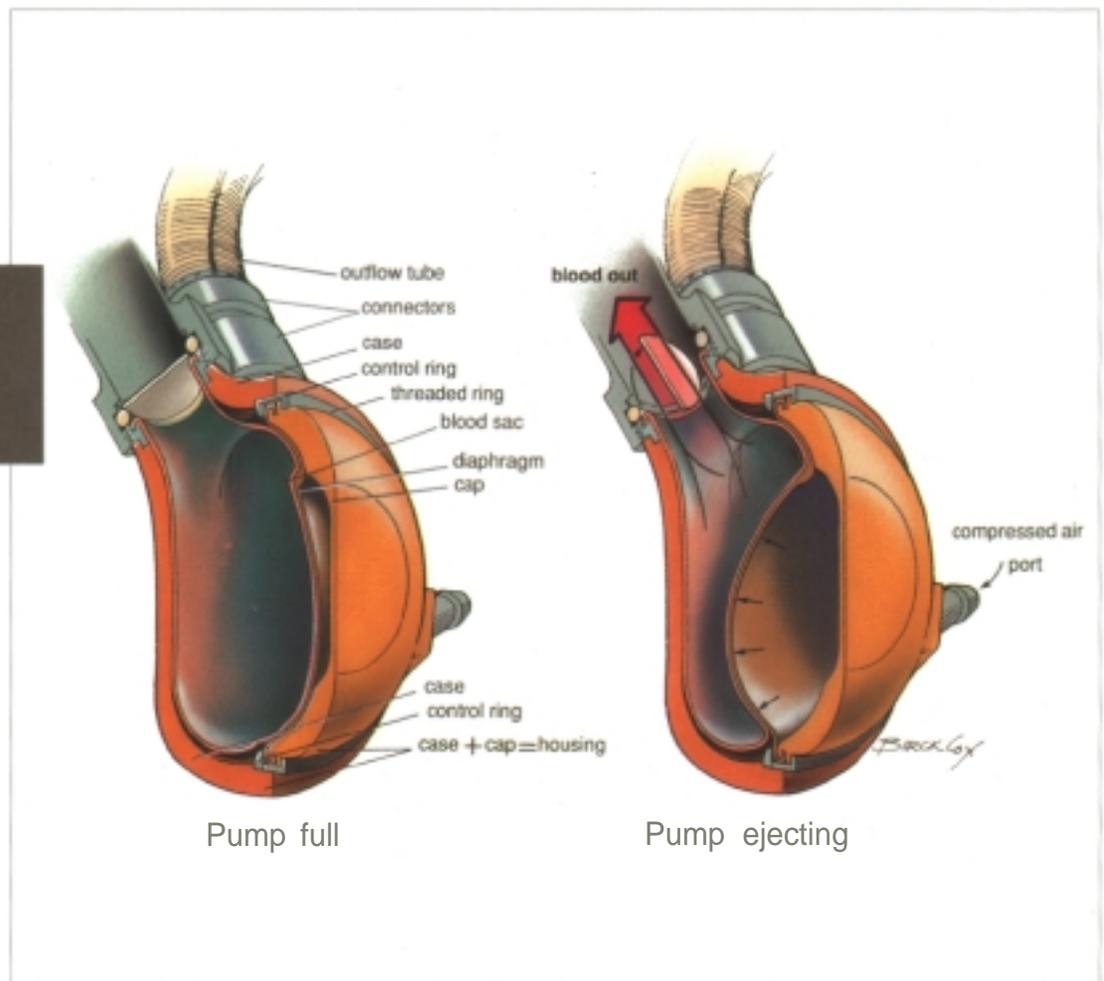
The attached heart-assist pump, which sits on the patient's abdomen, receives blood from the left atrium and returns blood to the ascending aorta.



DESCRIPTION OF THE PENN STATE HEART- ASSIST PUMP. The pump consists of a rigid plastic outer housing, initially made of polycarbonate, but changed to polysulfone in recent years. Within the housing is the extremely smooth, seam free blood sac. The housing has two components, the main pump case and the blood pump cap. The cap, with attached diaphragm, joins the case using a threaded ring. Air introduced through the port moves the diaphragm away from the cap. One-way heart valves control the pump's inlet and outlet tubes. Connectors secure the inlet and outlet tubes to the pump.

The air forced between the cap and case moves the diaphragm and pushes on the blood sac. The diaphragm limits the movement of the sac so the walls cannot contact each other and damage the living blood and adds a margin of safety in the event the blood sac ruptures. The driving air cannot enter the blood stream unless the diaphragm also is torn.

A cross-sectional view of the Penn State Heart-Assist Pump.



The shapes of the blood pump outer housing and the control ring are extremely important in the proper functioning of the pump. With different geometry, high strains could exist on the blood sac and failures would occur. Elementary stress analysis for the blood sac's critical flexing regions determined the proper geometry in the folding regions.

The control ring is positioned between the cap and the pump case and insures adequate space between the diaphragm and blood sac. The pump's circular shape, with parallel tangential ports and properly oriented tilting disc valves, provides a circular washing pattern that keeps blood moving throughout the cycle. This design minimizes clotting. Designers strove to eliminate areas of blood pooling, especially at connectors. Materials were selected for biocompatibility and a close electromotive series match to reduce corrosion.

The drive unit that powers the pump consists of high- and low-pressure tanks fed by an external air supply and circulated by an internal compressor. A pilot-operated spool valve, or in later versions a three-way solenoid, alternates pump exposure to the high- and low-pressure tanks. During the blood-filling phase (diastole), the low-pressure tank supplies the blood pump. During the ejection or emptying phase (systole), the high-pressure tank supplies the airline.

The drive unit employs two control methods. One control method synchronizes the pump with the patient's natural heart beat. The pump also can operate so that it begins the pumping phase as soon as the device is full. An electronic timer adjusts the frequency and duty cycle of filling and emptying. In both modes, the pump responds to the patient's body and pumps all the blood that is returned to it.

The pump's circular shape, with parallel tangential ports and properly oriented tilting disc valves, provides a circular washing pattern that keeps blood moving throughout the cycle. This design minimizes clotting.

CONTINUING RESEARCH ON THE PENN STATE HEART- ASSIST PUMP. The Penn State assist pump is now manufactured by Thoratec, Inc., in Berkeley, California, and Sarns/3M Health Care in Ann Arbor, Michigan. Research on the heart-assist pump continues and Sarns currently is investigating improved valves and improved polymers for the sac material.

The Penn State group and other biomedical research groups are applying the design principles developed for this pump in more advanced devices. With minor modifications, two heart-assist pumps served as a total artificial heart in three patients at Penn State's Milton S. Hershey Medical Center. The first such use was on October 18, 1985. On March 17, 1986, two pumps configured as a total artificial heart allowed the longest-surviving patient with the Penn State heart to live for 390 days.

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Application of these design principles to similar blood pumps is underway. These designs use small electronic motor drives with mechanical linkages to actuate the pumps. The Penn State group developed a permanent heart-assist pump and a totally implantable, electric, totally artificial heart pump using principles and knowledge gained from the previous work with pneumatic heart-assist pumps.

A left-ventricular-assist pump is attached to patient George Meisner. Mr. Meisner used the pump as a bridge to transplant and, as of March 1990, is actively employed and enjoying renewed health. Mr. Meisner would not have survived without the bridging time offered by the Penn State Heart-Assist Pump.



International Historic Mechanical Engineering Landmark

PENN STATE HEART-ASSIST PUMP

1976

The Milton S. Hershey Medical Center

The Pennsylvania State University

Hershey, Pennsylvania

This is the first extremely smooth, surgically implantable, seam free pulsatile blood pump to receive widespread clinical use. The pump pioneered the application of fluid-mechanics principles in blood-pump development and the use of segmented polyurethane as the blood-contacting material. An interdisciplinary group designed the pump using fundamental engineering principles and problem-solving techniques.

In its use in more than 250 patients, it has been responsible for saving numerous lives.

American Society of Mechanical Engineers

1990

BIOGRAPHICAL SKETCHES:

WILLIAM S. PIERCE, M.D.: Dr. Pierce is a chemical engineer and thoracic surgeon at Penn State. He is known worldwide for pioneering research in circulatory assist and artificial heart pumps. Dr. Pierce has published more than three hundred publications. He is an Evan Pugh Professor of Surgery (Penn State's highest academic award), as well as a Jane A. Fetter Professor of Surgery.

JAMES H. DONACHY: Mr. Donachy is director of fabrication in the Division of Artificial Organs at Penn State and is responsible for the design and manufacture of parts used in the assembly of the Penn State heart. He has four U.S. patents involving plastics and polymers and has two additional patents pending. He has co-authored more than fifty articles and abstracts and contributed to eight book chapters on artificial organs.

GERSON ROSENBERG, PH.D.: Dr. Rosenberg is a mechanical engineer who developed the Penn State mock circulatory system used to evaluate blood pumps and later established as a standard mock circulatory system by the National Institutes of Health. Dr. Rosenberg is research professor of surgery and associate professor of bioengineering and is assistant chief of the Division of Artificial Organs. His primary responsibilities include blood-pump design, specifically motor-driven, heart-assist, and totally artificial heart pumps. Dr. Rosenberg has written approximately one hundred publications.

JOHN A. BRIGHTON, PH.D.: Dr. Brighton is a mechanical engineer and was the original engineering collaborator with Dr. Pierce. He was chairman of the Department of Mechanical Engineering at Michigan State University and director of the School of Mechanical Engineering at Georgia Tech. He is currently dean of the College of Engineering at Penn State. Dr. Brighton has more than twenty publications in the area of biomedical engineering.

WINFRED M. PHILLIPS, D.S.C.: Dr. Phillips was one of the early collaborators with Dr. Pierce. He is a mechanical engineer who made significant contributions in the area of flow visualization and blood flow within the pump. Dr. Phillips left Penn State to become chairman of the Department of Mechanical Engineering at Purdue University and currently is dean of the College of Engineering at the University of Florida. Dr. Phillips has more than one hundred publications in the area of biomedical engineering and remains active in heart-valve research.

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IMPORTANT DATES IN THE HISTORY OF THE PENN STATE HEART- ASSIST PUMP

1970 Artificial Heart and Circulatory Support group established at Penn State

1975 Spring: Initial sketches of angled-port heart-assist pump

Summer: Initial pumps fabricated

Fall: Initial animal trials begin

1976 Summer: Approval by Clinical Investigation Committee for clinical use

December: First patient placed on heart-assist pump

1977 First long-term survivor following open-heart surgery

1980 Public Health Service contracts with Thoratec Laboratories Corporation to provide heart-assist pumps of the Penn State design to Saint Louis University

September 16: U.S. Patent #4,222,127 issued describing the major design features of the Penn State heart-assist pump

1985 The Clinical Registry of Mechanical Ventricular Assist Pumps and Artificial Hearts established at Penn State

1986 First successful application as a bridge for cardiac transplantation

1988 Multicenter study reports use of pump in twenty-nine patients as a bridge to cardiac transplantation

1989 To date, a total of eighty-five known survivors following use of this heart-assist pump

FOR FURTHER READING

William S. Pierce, M.D., and John L. Myers, M.D. Left Ventricular Assist Pumps and the Artificial Heart. *The Journal of Cardiovascular Medicine* 6(7):667-74 (1981).

William S. Pierce, M.D., et. al. Ventricular-Assist Pumping in Patients with Cardiogenic Shock After Cardiac Operations. *New England Journal of Medicine*, [Vol.]:305(27): 1606-10 (1981).

William S. Pierce, M.D. Artificial Hearts and Blood Pumps in the Treatment of Profound Heart Failure. *Circulation* 68(4):883-88 (1983).

John L. Pennock, M.D., Craig B. Wisman, M.D., and William S. Pierce, M.D. Mechanical Support of the Circulation Prior to Cardiac Transplantation. *The Journal of Heart Transplantation* 1(4):299-305 (1982).

Wayne E. Gaines, Gerson Rosenberg, John L. Pennock, and William S. Pierce. Development of a Long-Term Electric Motor Left Ventricular Assist System. *The Journal of Heart Transplantation* 3(4):323-28 (1984).

The Penn State Heart Assist Pump is the 29th International Landmark to be designated since 1973. In addition, there are ninety-four National and eleven Regional Landmarks, five Mechanical Engineering Heritage Sites and one Collection. Each represents a progressive step in the evolution of mechanical engineering, and each reflects its influence on society, whether it is of significance in its immediate locale, in the nation, or throughout the world. For more information about programs sponsored by the ASME History and Heritage Committee, please contact the ASME Public Information Department at 345 E. 47th St., New York, NY 10017; (212) 705-7740.

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