ABIOCOR®
FREQUENTLY ASKED QUESTIONS

What is the AbioCor®?
The AbioCor® Implantable Replacement Heart is not only the world's first completely self-contained, internal artificial heart but also the first internal artificial organ. Developed by Abiomed, Inc., the AbioCor is a product of three decades of research, development and testing. The AbioCor sustains the body's circulatory system and mimics the function of the human heart. It is designed not only to extend the lives of patients who would otherwise die of heart failure, but also to offer a satisfactory quality of life. The AbioCor is intended to replace the severely damaged natural heart for patients who have no other treatment alternative.

How many patients could potentially benefit from the AbioCor?
FDA approval of the AbioCor would be under the established guidelines for a Humanitarian Device Exemption (HDE). This means that AbioCor would be used selectively to treat no more than 4,000 patients in the U.S. each year.

What type of patient could benefit from the AbioCor?
The AbioCor is intended for use with patients who suffer from biventricular heart failure and for whom a heart transplant is not an option. Patients with other illnesses such as organ failure or cancer are in most circumstances kept off the heart transplant donor list. This is so the roughly 2,200 donor hearts can be given to the patients with the best chance of survival. Even so, we face a shortage of donor hearts compared to the current need.

How does the AbioCor work?
One of the most sophisticated implantable medical devices ever developed, the AbioCor is designed so that a patient can remain mobile and continue a productive lifestyle. The AbioCor is able to pump blood through the body, simulating the rhythm of a heartbeat. The complete AbioCor system consists of an internal thoracic unit, an internal rechargeable battery, an internal miniaturized electronics package and an external battery pack, handheld alarm monitor and sophisticated computer console.

The thoracic unit of the AbioCor, weighing approximately two pounds, includes two artificial ventricles with corresponding proprietary artificial valves which provide a seamless blood path, as well as a motor-driven hydraulic pumping system. The implantable electronics package monitors and controls the pumping speed of the heart based on the physiologic need of the patient. The AbioCor operates on both internal and external lithium batteries. The internally implanted battery is continually recharged from an external power source or from a basic patient-carried external battery pack. This is achieved with an energy transfer device called TET (transcutaneous energy transmission) which comfortably transmits power across the skin, without piercing its surface.

How long do the batteries last?
The device consists of an internal, rechargeable battery that is normally charged by the wireless external power source, the TET. External, portable battery packs can be used for many hours and allow the patient to be quite mobile. The internal battery of the AbioCor can be used on its own for approximately one half-hour, upon which the external pocket monitor system or console will activate an alarm. The internal battery is meant for brief support, such as for the time it takes to shower.

What is the AbioCor made of?
The AbioCor is primarily made of titanium and Angioflex®, Abiomed's proprietary polyether-based polyurethane. The AbioCor is designed to have relatively few moving parts. Moving parts such as the valves and ventricular membranes are manufactured from Angioflex, which has been tested by Abiomed to be safe for contact with properly flowing blood and flexible and durable enough to withstand beating 100,000 times a day (the approximate number of beats per day of the natural heart) for many years. The AbioCor's smooth and seamless construction and unique design are specifically engineered to reduce the likelihood of damage to blood cells.

What were the results of the clinical trial of the AbioCor?
Abiomed received approval of its IDE application to begin clinical trials in January 2001. The first patient was implanted on July 2, 2001. Fourteen patients were implanted with the AbioCor at four centers in the U.S., including Jewish Hospital in Louisville, KY., Texas Heart Institute at St. Luke's Hospital in Houston, UCLA Medical Center in Los Angeles, and Hahnemann University Hospital in Philadelphia. In this study some patients were able to resume their normal activities such as exercising, going to the movies, or out to dinner. One patient survived for 512 days with the device and was able to be there for the birth of his great-granddaughter.

What is different about the AbioCor compared to artificial hearts developed in the past?
The AbioCor incorporates many advances—such as the TET, miniaturized microprocessors and high capacity batteries—that were not available with the early predecessors. Earlier devices required patients to be tethered to large, external air-pumping consoles. In order to connect to these consoles, patients had tubing exiting skin sites, which increased their chances of infection. In contrast, the AbioCor is designed to be implanted fully within patients' bodies. The AbioCor eliminates the need for the patient to be permanently immobilized through tubes or wires connected to an external power source. As clinical experience is gained, patients are eventually expected to be able to leave the hospital and resume a more productive lifestyle than previously.

What is the difference between the AbioCor and a BiVAD device?
A BiVAD (bi-ventricular assist device) is the use of two blood pumping devices to assist the failing right and left ventricles. BiVADs are not an option for all patients as they are only intended to provide temporary support.

When will the AbioCor be available to patients?
Now that the AbioCor has been approved by the FDA under an HDE, the device will become available in a controlled roll-out at the clinical trial sites and additional qualified centers once they have completed rigorous training with Abiomed. Abiomed is in the initial phase of plans to pursue the CE Mark to make the AbioCor available to patients in Europe.

Is the AbioCor covered by insurance?
Not yet. Now that the AbioCor has received an HDE from the FDA, Abiomed is working with the Centers for Medicare and Medicaid Services (CMS) and private insurers to assist in their development of reimbursement guidelines for this medical device. Abiomed's other ventricular assist devices, the AB5000 and the BVS 5000 are both covered by most insurers.

What is the AbioCor II?
The AbioCor II is under development as the next generation of fully implanted artificial heart. The device is 30 percent smaller which should make it fit more patients in need of total heart support and has a target support time of over five years.