Smaller Implantable Heart Assist Device Approved

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The Food and Drug Administration has approved an implantable ventricular assist device that is markedly smaller than previously available devices and is the first that can be used in smaller adults, which will make this technology available to many more women with heart failure.

The agency announced the approval of the HeartMate II LVAS (Left Ventricular Assist System), a continuous flow left ventricular assist device manufactured by Thoratec Corp., for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular heart failure.

The device has a "novel design that is the first to mechanically support the weakened heart of a small-sized adult man or woman with heart failure who is at risk of dying while awaiting a heart transplant," the FDA said in a statement. It is intended for use inside and outside the hospital and is contraindicated in patients who cannot tolerate anticoagulation therapy.

The HeartMate II is smaller than the other available devices because it uses a continuous flow pump instead of the standard pulsatile pump. It is three inches long and weighs about a pound.

Dr. Daniel Schultz, director of the FDA's Center for Devices and Radiological Health, said in the statement that until this approval, "some heart transplant candidates have been underserved due to the large size of previously approved heart assist devices." Previously available devices have been too large to implant in many smaller patients.

The HeartMate II, an axial flow, rotary ventricular assist system that can generate flows of up to 10 liters of blood a minute, is attached to the apex of the left ventricle, and "diverts blood from the weakened left ventricle, and propels it to the rest of the body," according to the product labeling. The device is being studied as destination therapy.

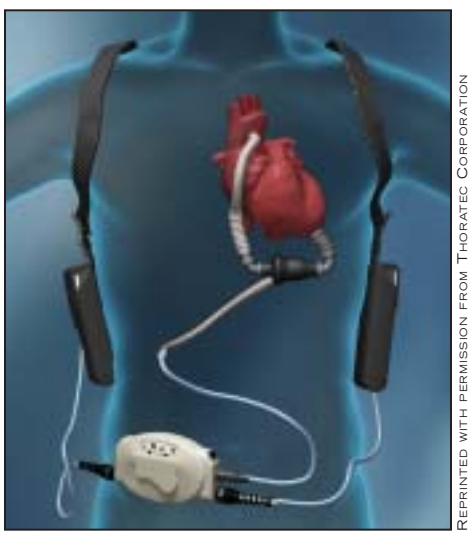
The HeartMate II is about one-seventh the size and about one-fifth the weight of previously available devices, and is noiseless, easier to implant, and easier to wear and tolerate than the previous generation of devices, said Dr. Leslie Miller, chair of cardiology, Washington (D.C.) Hospital Center, who is an investigator and author of studies of the device. Compared with Thoratec's XVE LVAD, which is about the size of a softball, the HeartMate II pump is about the size of a flashlight battery, he noted.

"It's a completely new technology," Dr. Miller said in an interview, noting that a major advance is that the device increases the availability of the technology to women, because previous devices were too big for many women, which is why about 90% of people in clinical trials of the devices have been men.

The HeartMate II can be implanted in women with a body surface area as small as 1.3 m^2, which is in the 90-100–pound range, and in smaller males, as well as in adolescents. With the previous devices, the lower limit was 1.5 m^2, which is about 130-140 pounds, said Dr. Miller. Thoratec has provided some funding for an investigator-initiated study with which he is involved.

At a meeting of the FDA's Circulatory System Devices Panel in November 2007, the panel unanimously recommended approval of the HeartMate II, with conditions that included a postapproval study, with a comparator, and the need to obtain more data in smaller patients (those with a body surface area of less than 1.3 m^2).

Thoratec said it will conduct a postapproval study of the HeartMate II, which will follow 169 recipients and will collect data on survival, adverse events, patient gender, small patients, and anticoagulation levels, and will include a comparator group. ■



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HeartMate II is connected to external equipment via a percutaneous cable.