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## FACT SHEET

### **Cedars-Sinai Heart Institute and the Sapien transcatheter aortic valve: Clinical trial of non-surgical intervention for aortic valve stenosis**

LOS ANGELES (June 20, 2008) – On Nov. 26, 2007, doctors at the Cedars-Sinai Heart Institute performed the first “transcatheter” minimally invasive replacement of an aortic heart valve in the western United States, using the Edwards SAPIEN transcatheter aortic heart valve developed by Edwards Lifesciences Corp. Cedars-Sinai is one of 16 centers participating in a pivotal clinical trial (the PARTNER trial) of the device, and is the only site currently recruiting on the West Coast.

The aortic valve controls blood flow from the heart’s main pumping chamber into the body’s largest arterial trunk. Stenosis (narrowing) at the valve reduces the outward flow of oxygenated blood and leads to congestive heart failure as the organ stretches to accommodate a greater-than-normal volume of blood.

While replacement mechanical or biological valves can be implanted, this is traditionally done via open-heart surgery. Many patients with aortic stenosis cannot be treated because they are not considered good candidates for surgery.

Transcatheter aortic valve replacement is accomplished in much the way blocked heart arteries are opened with balloon angioplasty and stents. A tube (catheter) containing a compressed balloon is inserted into a blood vessel at the groin and threaded up to the heart. The balloon is placed inside the damaged valve and inflated to open the narrowed area. A “stent valve” consisting of bovine pericardial tissue and a stainless steel frame is then placed on the catheter, threaded up to the heart, put into position and the balloon is inflated to expand the valve and press it into the calcified tissue on the artery wall. The balloon catheter is then removed, leaving the new, functioning valve in place.