CEDARS-SINAI MEDICAL CENTER. NEWS

8700 Beverly Blvd., Room 2429A ■ Los Angeles, CA 90048-1865
Office (310) 423-4767 ■ Fax (310) 423-0435

Media Contact: Sandra Van
E-mail: sandy@vancommunications.com
Telephone: 1-800-880-2397

FOR IMMEDIATE RELEASE – July 2, 2002

AVAILABLE FOR INTERVIEWS:
Saibal Kar, M.D., Adult Interventional Cardiologist Ayelet Kotel, 27, of Woodland Hills, Patient

HIGHLIGHTS: Thanks to the Larry King Cardiac Foundation and the unwillingness of two Cedars-Sinai cardiologists to "give up," a 27-year-old Woodland Hills (CA) mother of two has become one of the first patients at Cedars-Sinai Medical Center to have an atrial septal defect (ASD) repaired non-surgically. Historically, the only treatment available for ASDs was open-heart surgery, but this non-surgical procedure was performed in 35 minutes while the patient was awake.

THANKS TO THE LARRY KING CARDIAC FOUNDATION AND A NEW ASD CLOSURE DEVICE, A 27-YEAR-OLD WOODLAND HILLS WOMAN HAS AVOIDED OPEN HEART SURGERY AND HAD HER HEART DEFECT REPAIRED NON-SURGICALLY

LOS ANGELES, CA (July 2, 2002) – It looks like a yo-yo, but it can stretch, flatten out, "swell up," or even "self-center," depending on what it needs to do to adjust itself to plug holes in the heart that make up some of the most common congenital heart defects. In the past, treating such heart defects required open-heart surgery, but thanks to these high-tech titanium devices that look like toys, surgery is no longer necessary. Amplatzer closure devices, long in use in Europe, received FDA approval earlier this year and are now being implanted non-surgically into adults and children at Cedars-Sinai Medical Center – with outstanding results.

Ayelet Kotel, age 27, a native of Natanya, Israel, and now a teacher's assistant at the Kadima Hebrew Academy in Woodland Hills, was diagnosed with an atrial septal defect (ASD) shortly before she became pregnant in 1997. Despite the fact that she was chronically short of breath, the doctors she was seeing then urged her to wait to have the defect repaired, as they did not believe it required immediate attention.

Although she waited several years, Ayelet worried constantly about the hole in her heart. After the births of her two children, she decided to ask her doctors to proceed with surgery. However, they continued to believe that repair was unnecessary. So she sought a second opinion and changed insurance companies. Her new doctor, Yzhar Charuzi, M.D., a cardiologist at Cedars-Sinai Medical, confirmed the diagnosis and referred her to Neal Eigler, M.D., and Saibal Kar, M.D., for consideration of closure of her ASD.

After examining her heart, both doctors felt that the defect – a large one – should be repaired , as failure to do so could lead to complications such as arrhythmias, pulmonary hypertension and even a stroke. Until very recently, treating ASDs required open heart surgery, but Dr. Kar told her about a new procedure he believed the FDA would soon be approving. The new ASD Closure Device was currently in use in Europe and had

-more-

proved to be very effective. Best of all, it would mean that she would not have to have surgery; she would recover very quickly and she wouldn't have the large scar that accompanies open heart surgery.

He encouraged Ayelet to wait a while longer and see if the device became FDA approved, which it did in early 2002. But as they made plans to move forward with repairing the defect, there was an unexpected hitch. Because her condition was classified as "pre-existing," her insurance company refused to pay for the repair.

However, Dr. Eigler and Dr. Kar were unwilling to give up, believing that Ayelet needed the repair as soon as possible. With help from, and the recommendation of Cedars-Sinai's director of cardiology, P. K. Shah, M.D., the Larry King Cardiac Foundation agreed to help Ayelet at once. She would become one of the first patients at Cedars-Sinai to have her heart defect treated non-surgically with the new closure device.

Dr. Kar explained in detail what he would be doing during the procedure. Instead of being done in a typical operating room, Ayelet's procedure would be performed in the heart catheterization laboratory. She would lie on an x-ray table and an x-ray camera would move over her chest during the procedure. In addition, he would use ultrasound imaging which would allow him to see the hole in her heart and position the closure device in it properly. Using only a local anesthetic, a small ultrasound catheter, or tube, would be inserted through her groin and threaded through large veins directly into her heart for visualization and positioning of the device. This would avoid the need for general anesthesia and insertion of an ultrasound catheter through her mouth.

He would then perform an angiogram (x-ray of blood vessels or heart chambers) to visualize her heart and the closure device. Then he would measure the pressure and oxygen content in different chambers of Ayelet's heart and measure the size of the hole in her heart.

Next, he would choose an appropriately-sized closure device – made of nickel and titanium alloy so it can be molded and stretched – and attach it to a tiny cable that would be threaded through the cathether until it reached the site of Ayelet's heart defect. At that point, he would push the closure device out of the catheter and into the defect, positioning it centrally in the hole, so that the two disks of the "yo-yo" would rest on each side of the hole. Once he was satisfied with the positioning of the device, he would release it by unscrewing the cable that had been used to slide it through the catheter. The two disks of the "yo-yo" would then expand and center themselves to fully plug the hole in her heart. The cable and catheter would then be removed and the implant would be complete.

Ayelet had the option of using a general anesthesia and "sleeping" throughout the procedure, or of using a local anesthetic and remaining awake. She opted to stay awake, and the procedure, done using only a "local," took about 35 minutes – compared to about three hours for open heart surgery. Although Ayelet was asking to go home two hours later, Dr. Kar persuaded her to stay overnight for observation.

Her results have been outstanding. "It's great not having to worry about that hole in my heart," she says. "Even though I 'could' exercise before, I haven't for the past two years because I was afraid to. Now I can --without worrying," she says. In addition, Ayelet has had both of her sons, ages 4-1/2 and nearly 3, tested. Neither of them have ASDs, for which she is profoundly thankful. "I'm very glad I had my defect repaired," she adds. "I had wonderful, incredible doctors at Cedars-Sinai."

Since the closure devices were approved by the FDA earlier this year, Cedars-Sinai cardiologists have implanted more than two dozen.

###