About Cardiac Surgery -> Non-Surgical Closure of Atrial and Ventricular Septal Defects

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Over the last 20 years significant research has been performed to design devices to close septal defects without the need for open heart surgery. These devices are passed through catheters advanced from the blood vessels that run in the groin.

Device Closure of Atrial Septal Defects

In September 2001, the FDA approved the first ever intra-cardiac device to close the most common type of atrial septal defect, the secundum atrial septal defect. This device is manufactured by AGA Medical and is known as the Amplatzer® Septal Occluder Device. The device is made of Nitinol (a nickel and titanium alloy), and consists of two discs with a connecting waist. The waist plugs the hole or defect and the discs provide support and hold the connecting waist in position. This device implant has proved to be very effective and safe method of closing ASDs. For more information go to www.amplatzer.com.

The other devices, which are still under investigation, available to close secundum atrial septal defects are the HelexÒ Septal Occluder manufactured by W.L. Gore (www.goremedical.com/products/HELEX/index.htm) and the STARFlex or CardioSEAL Septal Occluder (www.nmtmedical.com) which is manufactured by NMT Medical.

The Pediatric Cardiac Center at Children's Hospital and Research Center at Oakland has been involved from the onset of clinical trials with the Amplatzer and the Helex devices and has performed many device closures of secundum atrial septal defects. Drs. Saba and Patel perform these procedures and would be happy to provide additional information about these devices.

Device Closure of Ventricular Septal Defects

The CardioSEAL Septal Occluder has been commercially approved in the USA by the FDA for limited indications using a FDA approval process called Humanitarian Device Exemption in types of ventricular septal defects under its humanitarian use exemption. The indications for ventricular septal defect device closure are very specific and if you or your child has a defect suitable for device closure, this option will be discussed with you. AGA medical is also researching two VSD devices, which are currently undergoing clinical studies and it is hoped that the Children's Hospital and Research Center at Oakland will be a study site.

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