HIGH TECH, WITH A MOTHER'S TOUCH

After Bao was diagnosed with an ASD, she went to her mother, Mai, who helps build the Abbott device to fix the problem.

Her cough never seemed to let go, a near constant presence in her life.

She had no stamina.

She just didn't feel right.

But she'd felt that way for so long, she didn’t know how to feel like anything else. And so that became her normal.

This was life.

It was that way when Bao Lee went in to urgent care feeling shortness of breath. She’d had a cold that had lasted a couple of weeks by that point, longer than it should have, really. A visit to the doctor's office would take care of it. She figured they'd listen to her, order up some antibiotics and she'd eventually shake it, at least for a little while.

It was all very routine.

It turned out to be anything but.

"Listening to my heart, the doctor said, 'You have a heart murmur,'" Bao said.

Concerned, her doctor ordered more tests. An echocardiogram known as a bubble test visually showed what had been heard in her stethoscope. Bao had an atrial septal defect (ASD), a hole in the "wall that separates the top two chambers of the heart," as the American Heart Association (AHA) defines it.

Left untreated, it can lead to heart failure and stroke.Bao knew she had to get it fixed.

"I thought of my daughter: Oh my gosh, what if I don't live long enough to see her grow up?' You start thinking all this stuff," Bao said.

She'd had it since birth. She wasn't sure why it wasn't discovered before she was in her 20s and a mother to baby Emma. Luckily for Bao, finding a fix did not take as long as her diagnosis.

An Abbott AMPLATZER™ Septal Occluder, which, when open, looks a bit like a butterfly wing, would be inserted into Bao's heart via a catheter through a vein in her leg. Once it was at the hole in Bao's heart, it would open up on both sides of the septal wall to close the defect.

As these things go, it was a relatively routine, minimally invasive procedure.

Routine. There's that word again. Sure, any procedure that's not your own can be described that way. But the planning for this particular procedure turned out to be anything but.

For nearly two decades, Bao's mother Mai has worked at Abbott as a member of the team that builds those very occluders, including the one that would go into Bao's heart.

"I could not sleep, thinking about it every day," Mai said. "What can I do to help her?"

Mai's job is to execute a final inspection before devices are packaged for delivery to doctors. The occluder destined for her daughter? Mai was determined that nothing would divert it from her careful hands and experienced eyes before ending up in Bao's heart. At Abbott, employees are reminded that they should treat products as if they were for their own family. In this case, it was.

"It made it real easy to talk to my mom about it," Bao said. "She understood."

The procedure went off without a hitch. After a short recovery, Bao was feeling better, back to chasing after little Emma. Her lingering bouts of cough are a thing of the past. Her exercise endurance is increasing. Her future with her growing family has never been brighter.

Ever since I got the device, I feel less fatigue. I used to tire out really easily. Now my energy level is up," Bao said. "I've been exercising a lot more. Recently I have been running. My husband and I were joking, 'Hey, we should run a 5K to celebrate.'"

And her mother Mai, sleepless for those weeks leading up to the day, rests easy.

"Now I can sleep. I sleep well," Mai said.

High tech, with a mother's touch.

"I feel like it is kind of fate. I just feel like it was destined to be. She's my mom, she's been there for me forever and now look, what she does for work is making a difference in my life now too," Bao said. "But I never really put it into perspective of, 'Mom saves lives,' you know? It's cool that my mom gets to make that impact."

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications for Use

The AMPLATZER™ Septal Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who now require closure of the fenestration.

Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload (such as, 1.5:1 degree of left-to-right shunt or RV enlargement).

Warnings

Physicians must be prepared to deal with urgent situations, such as device embolization, which require removal of the device. This includes the availability of an on-site surgeon. Embolized devices must be removed as they may disrupt critical cardiac functions. Embolized devices should not be withdrawn through intracardiac structures unless they have been adequately collapsed within the sheath. Use on or before the expiration date noted on the product packaging. This device is sterilized using ethylene oxide and is for single use only. Do not reuse or resterilize. Attempts to resterilize the device may result in device malfunction, inadequate sterilization, or patient harm. Do not use the device if the packaging sterile barrier is open or damaged. Do not release the AMPLATZER™ Septal Occluder from the delivery cable if the device does not conform to its original configuration, or if the device position is unstable or if the device interferes with any adjacent cardiac structure (such as Superior Vena Cava (SVC), Pulmonary Vein (PV), Mitral Valve (MV), Coronary Sinus (CS), aorta (AO)). Recapture the device and redeploy. If still unsatisfactory, recapture the device and either replace with a new device or refer the patient for alternative treatment. Implantation of this device may not supplant the need for Coumadin™ in patients with ASD and paradoxical emboli. The use of echocardiographic imaging (TTE, TEE, or ICE) is required. Balloon sizing should be used to size the atrial septal defect using a stop-flow technique. Do not inflate the balloon beyond the cessation of the shunt (such as, stop-flow). DO NOT OVERINFLATE. Patients with a retro-aortic rim of less than 5 mm in any echocardiographic plane, or patients in whom the device physically impinges on (i.e. indents or distorts) the aortic root, may be at increased risk of erosion. Do not select a device size greater than 1.5 times the echocardiographic-derived ASD diameter prior to balloon sizing.

Potential Adverse Events

Potential adverse events may occur during or after a procedure placing this device may include, but are not limited to: Air embolus, Infection including endocarditis, Allergic dye reaction, Need for surgery, Anesthesia reactions, Pericardial effusion, Apnea, Perforation of vessel or myocardium, Arrhythmia, Pseudoaneurysm including blood loss requiring transfusion, Cardiac tamponade, Tissue erosion, Death, Thrombus formation on discs, Embolization, Stroke, Fever, Valvular regurgitation, Hypertension/hypotension.