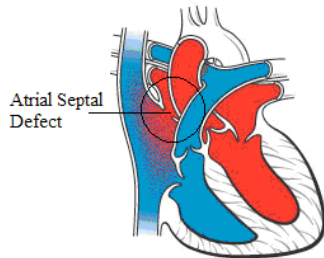


AMPLATZER® Septal Occluder

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Atrial Septal Defect (ASD) is a congenital heart defect that will require 2,500 people to have repair performed each year. This condition is usually detected at a young age in children. The abnormality occurs when the heart wall between the left and right atria does not close properly. ASD often presents no detectable symptoms. An individual would have no idea they have a hole in their heart. Someone with a large hole in their heart might experience symptoms such as: poor appetite, poor growth, fatigue and shortness of breath. Often, a doctor will diagnose the condition when they hear a heart murmur during a physical examination. An echocardiograph can confirm if the individual has ASD.

What is happening inside a heart with ASD is that oxygenated blood from the left atrium is flowing into the right atrium. Now, an increased volume of blood is flowing from the right atrium into the pulmonary artery and into the lungs. As a result there is an inefficiency, because already oxygenated blood is displacing blood that needs to receive oxygen from the lungs.

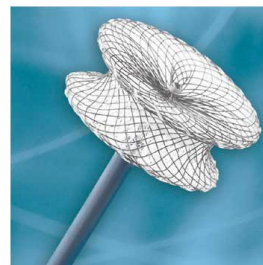


If ASD is not treated while a person is a child (or when young), more serious problems can occur later in life. Abnormal heart rhythm and problems with heart function could occur, and this could lead to heart failure. An increased risk of stroke is also a risk for someone with untreated ASD.

There are two different treatment options for ASD. The first method is open heart surgery, which is an invasive technique where the surgeon will either suture the hole, or use a patch. A much safer and less evasive way is the use of the AMPLATZER® Septal Occluder. This device is placed inside a catheter and placed inside the heart to seal the hole. The AMPLATZER® Septal Occluder was invented by Dr. Kurt Amplatz, a researcher at the University of Minnesota.

The AMPLATZER® Septal Occluder was approved by the FDA in December 2001, and has no complications in 99% of the cases. This high success rate and the fact that the patient doesn't need to go through open heart surgery makes this device desirable and preferable. The AMPLATZER® Septal Occluder can close holes that range from 4mm to 38mm in size. The device is made of a wire mesh called Nitonal, which is an alloy from nickel and titanium. Nitonal has a shape memory which allows it to return to its original shape after being compressed in a catheter.

The surgeon will place the AMPLATZER® Septal Occluder into a catheter, and thread it through the patient's femoral vein, through the inferior vena cava, and into the site of the ASD. The first part of the disk is released into the left atrium, pulled against the septum so the waist can fill the hole, and then the other disk is released into the right atrium. This forms a "clamp" and seals the hole. The AMPLATZER® Septal Occluder is filled with polyester fabric inserts, which provide a foundation for tissue growth after the procedure. Generally, the heart tissue will take three to six months to completely cover the device. The procedure takes only one or two hours, and post procedural hospital stay is less than 24 hours. The only complications that have resulted from the use of this device have been the formation of blood clots. If properly monitored, medication can counteract this side effect.



References:

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