SeptRx

Product Profile:
The SeptRx® IPO

At last, a 100% effective, minimally invasive device designed to block a hole in the heart: *SeptRx® IPO for PFO*

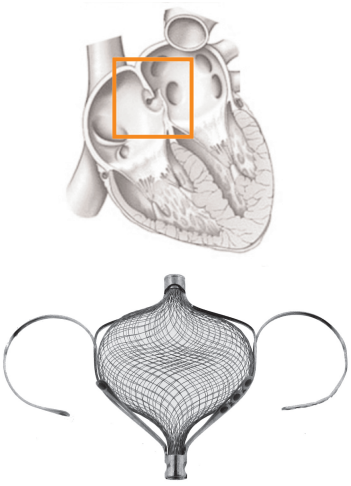
The *SeptRx® Intrapocket PFO Occluder* (IPO) is an elegant, next-gen medical device—the only *patent foramen ovale* closure device with 100% closure and 100% safety based on 3-year follow-up data on patients.

SeptRx's strategy is to complete its European PFO clinical trial this year, commercialize its breakthrough device throughout Europe, and then seek the FDA's consent to begin a U.S. trial.

The SeptRx® IPO is designed to block a hole in the heart.

Each year about 770,000 Americans suffer a stroke, 25% of which are recurrent attacks. There is significant retrospective evidence that PFO closure is effective for reducing the incidence of stroke, but no large-scale trial has proven the connection, and thus the importance of the SeptRx® IPO clinical trial underway in Europe.

World's First and Only PFO-Closure Device with 100% Closure Rate and 100% Safety out to 3 years



SeptRx® IPO—Intrapocket PFO Occluder

SeptRx® IPO F-I-H Clinical Study Results

- 11 patients
- 100% closure
- No device migration
- No adverse events
- ≥3-year follow-up, no issues

Pilot study results have led to an ongoing pivotal clinical study.

The SeptRx® Intrapocket PFO Occluder (IPO) consists of a laser-cut, electropolished Nitinol frame and an internal fine-wire Nitinol mesh. The SeptRx® IPO is a medical device for percutaneous transcatheter closure of a heart defect known as patent foramen ovale (PFO). The presence of a PFO has been identified as a contributing factor in cryptogenic stroke, chronic migraine, decompression sickness, and obstructive sleep apnea.

While it is commonly referred to as a "hole" in the heart, a "PFO" is actually a *tunnel*-like opening between the upper chambers of the heart. We are all born with this "hole" as it is a critical part of the fetal circulation, but it usually seals itself within a few months after birth. In about 25% of the population it does not fully close and therefore can allow emboli in the blood to pass between the right and left atria (thereby bypassing the natural "filter" of the lungs) and eventually making their way into the arteries of the brain.

The SeptRx® IPO's self-expanding Nitinol frame is designed to fit a wide range of PFOs and, when deployed, expands laterally to gently flatten the pocket of the PFO to appose the septal tissues.

The initial implant width is 14 mm, which is designed to treat about 70% of PFOs. A 19-mm implant is in development and will be completed prior to commercial release in order to accommodate the full range of treatable PFO widths.

At the top of the device are "scroll" anchors designed to unfurl and adapt to a variety of PFO tunnel lengths. These anchors grip the left atrial edge of the PFO tunnel to provide positive anchoring. At the base of the IPO implant are additional anchors that are designed to grip the edge of the PFO tunnel on the right atrial side.

Both left and right atrial anchors contain radiopaque markers to assist in proper device orientation during delivery. The mesh provides an immediate barrier to the conduction of emboli and also is intended to stimulate the body's natural adhesion response for permanent closure of the PFO.

What the experts are saying...

Horst Sievert, MD
CardioVascular Center of Frankfurt
"I strongly believe that we have to select PFO devices according to the individual anatomy of the interatrial septum. In-tunnel devices are a major step forward. In particular, the data from the SeptRx® IPO pilot study are encouraging."

John D. Carroll, MD
University of Colorado Hospital
"Safe, effective closure devices are certainly an ongoing need for treating patients whose strokes are related to the presence of a PFO."

Scott Russell
CEO, SeptRx
"As more is learned of the potential role PFO plays in stroke, it may be possible to expand the application of PFO-closure devices into migraine and other conditions."

NOTICE: The SeptRx® IPO is not approved for sale in any regulatory jurisdiction. Further, it is not yet available for investigational use or commercial sale in the U.S.