

SeptRx

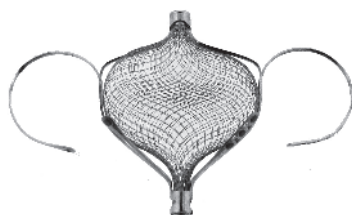
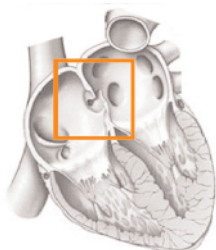
Company Fact Sheet

SeptRx, Inc. is an emerging medical device company that is developing the **SeptRx® Intrapocket PFO Occluder (IPO)**, a platform for the percutaneous transcatheter closure of a heart defect known as **patent foramen ovale (PFO)**. PFO is a tunnel-like defect connecting the right atrium with the left atrium. A remnant of fetal circulation, it usually seals itself within a few months after birth. Unfortunately, in about 25% of the population the PFO does not fully close and may allow blood (and emboli) to pass directly between the right and left atria. The presence of a PFO has been identified as a contributing factor in cryptogenic stroke, chronic migraine, decompression sickness, and obstructive sleep apnea. A PFO contributes to these conditions by providing a pathway for emboli (blood clots, air bubbles) in the venous system to reach the arterial system by passing directly from the right atrium to the left.

The potential combined PFO market in the United States and Europe is conservatively estimated at \$1 to 4 billion annually in just the areas of stroke and migraine. Depending on the degree of broader worldwide market development and expansion into additional patient subsets or indications, the fully-realized worldwide market for PFO closure devices could be over \$5 billion annually, and possibly as high as \$20 billion.

Unlike most other PFO devices that are based on devices originally designed for closure of atrial septal defects (ASDs), the SeptRx® Intrapocket PFO Occluder has been designed to address the unique anatomical and physiological challenges of the PFO (see illustration below). For example, the SeptRx® IPO directly treats the pocket of the PFO and is designed to minimize impact to the atrial spaces. Another unique feature is the flat frame of the SeptRx® IPO, which applies a gentle force to the PFO tunnel to laterally stretch the tissues and flatten the pocket of the PFO to bring the septal surfaces together and trigger the body's natural adhesion response. Additionally, the SeptRx® IPO's internal mesh is designed to promote permanent occlusion of the tunnel while simultaneously providing immediate inhibition to the conduction of emboli. The SeptRx® IPO is delivered via a low-profile (9 French) transcatheter delivery system for increased safety and ease-of-use, and is fully recapturable.

The SeptRx® Intrapocket PFO Occluder has already completed a successful 11-patient first-in-human (FIH) clinical trial. SeptRx's FIH trial was the first and only PFO device trial to demonstrate 100% closure and 100% safety (out to 3 years). A larger European clinical trial is currently underway: **InterSEPT** (In-tunnel SeptRx European PFO Trial), from which data will be used to apply for CE marking. The trial is being conducted at two investigation sites: Frankfurt, Germany, and Massy, France.



Heal the Heart. Protect the Brain.™

A *patent foramen ovale* (PFO) is an unsealed tunnel between the right and left atria of the heart (left, top). In about 25% of us, the *foramen ovale* does not completely seal after birth and remains "patent" or open. In patients with a PFO, the tunnel can reopen from coughing or straining, providing a pathway for blood clots to travel to the brain.

The SeptRx® Intrapocket PFO Occluder (IPO) (left, bottom) is a medical device for percutaneous transcatheter closure of the heart defect PFO. The internal mesh of the SeptRx® IPO promotes permanent closure of the tunnel while simultaneously providing an immediate inhibitor to the conduction of emboli, which could block a blood vessel in the brain.

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.

CONTACTS & KEY INFORMATION

Website	www.septrx.com
Ownership	Privately held
Financing	Early stage
Corporate Investors	NDC (Nitinol Devices & Components) Inc., Stout Medical Group LP
Sector	Medical technology
Platform	Intrapocket PFO Occluder (IPO)
Positioning	Best-in-class, next-generation solution for closure of PFO (patent foramen ovale)
Stroke/TIA Market	Cryptogenic ischemic recurrent strokes/TIAs, with PFOs
Migraine Market	Weekly, severe migraineurs who have aura, with PFOs that are refractory to Tx

LEADERSHIP

Scott Russell
President, CEO, Director;
Co-Inventor of the SeptRx IPO

Beverly Tang, PhD
Technical Project Leader

Steve Kleshinski
SeptRx Director and CSO;
VP, Advanced Device Concept Group, NDC;
Primary Inventor of the SeptRx IPO

Tom Molz
Chairman of SeptRx;
President and CEO, Stout Medical

Tom Duerig, PhD
SeptRx Director;
President and CEO, NDC

Skott Greenhalgh, PhD
SeptRx Director;
CTO, Stout Medical;
and Co-Inventor of the SeptRx IPO