



News Release

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Stentys appoints Luc Morisset as Director of Regulatory Affairs

Company seeks to position its *second-generation dedicated* stent for treatment of blocked coronary artery *bifurcations* as simple and effective as a conventional stenting procedure

“Given our intent to begin first-in-man studies by mid-year, Luc’s addition to our management team is certainly an important and timely event.”

Gonzague Issenmann, Co-Founder and CEO, Stentys

PARIS, Feb. 21, 2007—Stentys (www.stentys.com) announced today that it has appointed Luc Morisset as its Director of Regulatory Affairs. Stentys is developing the *world’s first second-generation dedicated* drug-eluting stent for treatment of blocked coronary artery *bifurcations* so that hundreds of thousands of patients might avoid open-chest surgery.

Previously, Luc Morisset was Director of Regulatory Affairs for Paris-based MedPass International, which assists manufacturers in bringing new medical technologies to the European market. In his 10 years at MedPass, Luc Morisset helped numerous companies by developing regulatory strategies to expedite CE marking and clinical trial approvals and to pave the way to FDA approval. Earlier in his career, he served for more than five years at the French Ministry of Health, responsible for the French pre-market approval process of certain medical devices, including pacemakers, and also as lead auditor and technical file assessor for CE marking of active implants at G-MED, the French Notified Body. Prior to joining the Ministry of Health, Luc Morisset worked as a hospital biomedical engineer after earning a degree in biomedical engineering from the UTC University in Compiègne, France.

“Luc Morisset brings more than 20 years of experience in EU regulatory affairs to Stentys, and no doubt will play a critical role in helping Stentys to make treatment of blocked coronary artery bifurcations as simple and effective as a conventional stenting procedure,” said Stentys’ CEO and co-founder, **Gonzague Issenmann**.

“The addition of Luc Morisset to the management team is a very significant milestone for Stentys,” added **Jacques Séguin, MD, PhD**, co-founder and Chairman of the Board of Stentys, who also is Chairman, CEO and founder of **CoreValve**. “His vast experience and outstanding track record will serve Stentys well, particularly at this important stage where first-in-man studies are on the near horizon.”

Coronary artery disease is caused by fatty lesions that narrow the coronary artery’s inside diameter (*stenosis*), consequently reducing the blood flow and depriving the heart muscle of oxygen. The dramatic consequence of this blockage is an often-lethal myocardial infarction. *Bifurcation* is the area where one main vessel branches out into two smaller vessels, one being the continuation of the *main vessel*, and the other often referred to as the *side branch*. Narrowings at a bifurcation site are quite common. Indeed, 18 percent of percutaneous coronary interventions involve a bifurcation stenosis. Of those, *restenosis* (re-occurrence of the blockage) occurs in 20-25 percent of bifurcations treated with drug-eluting stents (DES).

The patent-pending innovation of Stentys’ bifurcated stent is that the stent-opening for the side branch can be created *anywhere* in the stent *after* it is implanted in the vessel. In short, the procedure’s success is independent from accurate positioning. The Stentys procedure is performed in three simple steps: (1) Stentys is implanted in the main vessel with an *approximate* positioning, like a standard stent; (2) the cardiologist chooses the optimal location for the side branch opening by inserting a balloon through the stent mesh, which is a cath lab-standard procedure; and, (3) the balloon inflation disconnects the mesh and creates the opening—Stentys’ self-expanding property allows the *in situ modeling* of the stent to fit the patient’s unique arterial anatomy.

Based in Paris, Stentys intends to make treatment of blocked coronary artery *bifurcations* as simple and effective as a regular stenting procedure.

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