MINVASYS

Amazonia®

Sir

Sirolimus Elution

SIRegistry

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1 INTRODUCTION

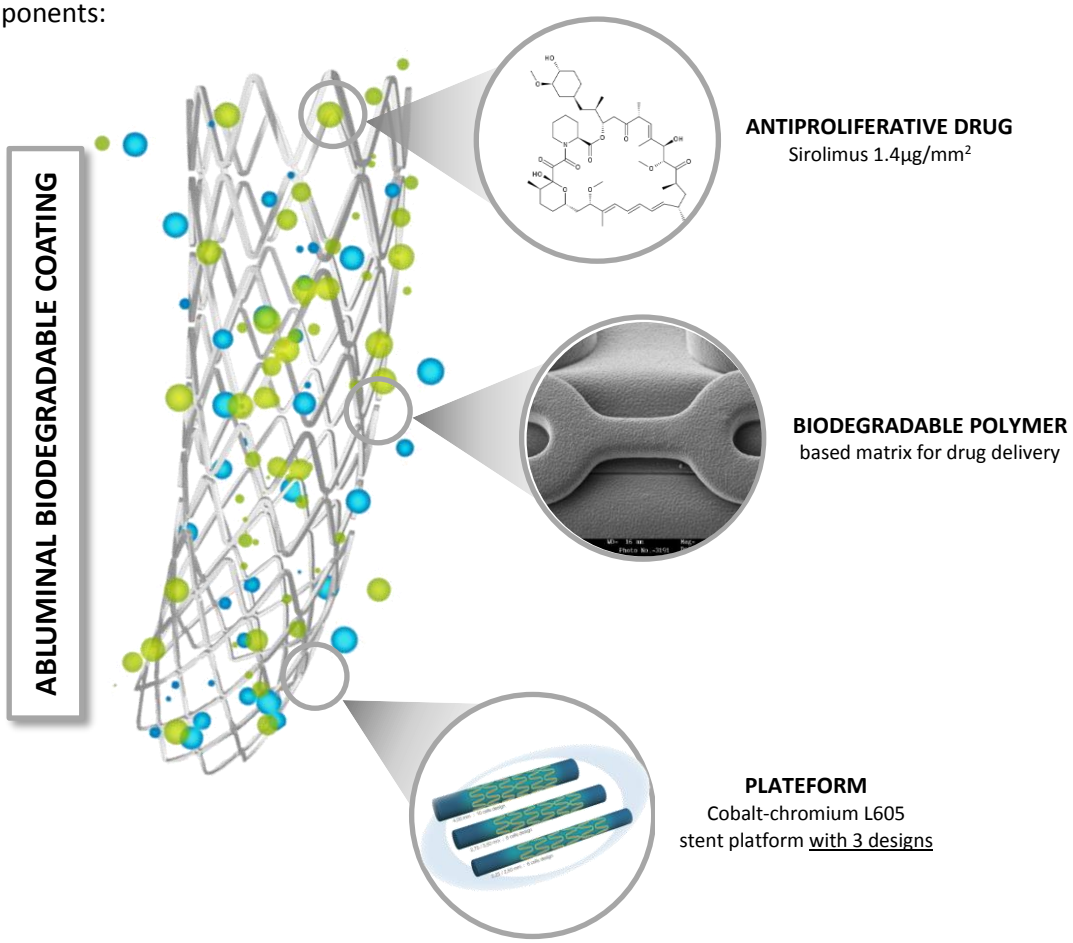
Concerns have been raised regarding the long-term safety of drug-eluting stents. The presence of a permanent polymer coating may cause stent thrombosis as a result of delayed healing and a hypersensitivity reaction in some cases.

To address this issue, new generations of DES may incorporate biodegradable, biocompatible polymers as vehicles for drug delivery.

In this objective, MINVASYS developed the Amazonia SIR, a Sirolimus-Eluting Stent (SES) with Biodegradable-Polymer (BP) matrix associated with a thin strut stent design for the treatment of coronary artery diseases. After achieving the first-in-man trial and the Amazonia SIR e-Registry, a registry was undertaken to confirm the safety and efficacy at 12 months of the Amazonia SIR stent in a worldwide real-world population. The study design and results are presented in this document.

2 DEVICE DESCRIPTION

The Amazonia SIR is a biodegradable polymer based drug eluting coronary stent. The device includes three main components:



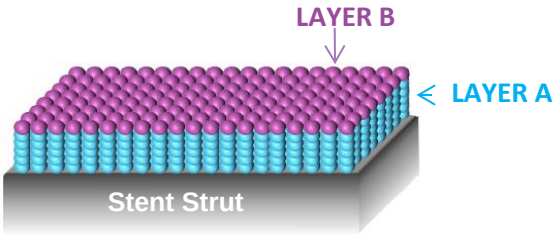
Anti-proliferative drug - Sirolimus

The device coating is a combination of inactive and active component. The active component is an anti-proliferative drug, sirolimus. Sirolimus also known as rapamycin, is an immunosuppressant drug that prevents activation of T cells and B-cells by inhibiting their response to interleukin-2 (IL-2).

The anti-proliferative effect of sirolimus prevent restenosis in coronary arteries. Sirolimus is formulated in blend of polymer coating that provides controlled release for a longer duration post coronary intervention.

Biodegradable polymers

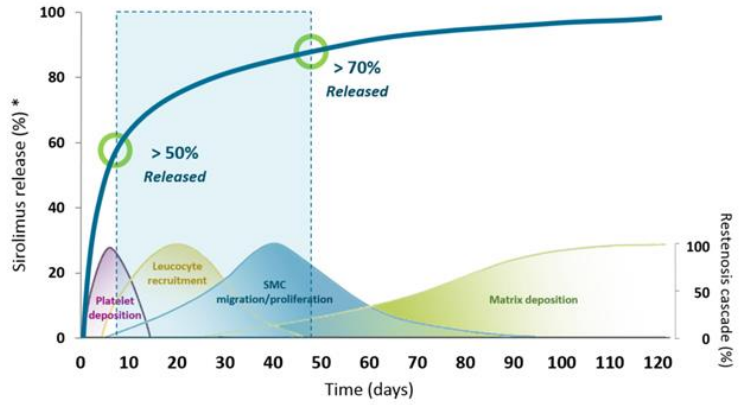
The inactive component is a Poly L-lactide based family of polymer (biodegradable and biocompatible polymer) which is released with the drug and totally degraded after 6 to 8 months.

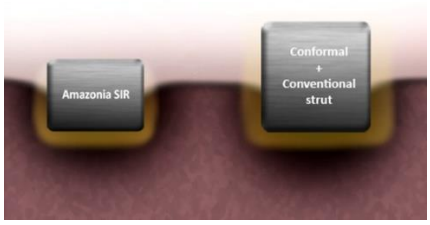


LAYER A - **Sirolimus drug** and **Poly-L lactic Acid** (PLLA), **Poly(lactic-co-glycolic) acid** (PLGA), **Polyvinylpyrrolidone** (PVP)
Bio-absorbable, biocompatible and non-toxic polymers.
LAYER B - **Poly Vinyl Pyrrolidone** (PVP)
100% Protective layer without drug.
Biodegradable, water soluble polymer.

Sirolimus controlled elution

The combination of two layers coating technology and abluminal drug distribution ensure an effective and controlled elution of sirolimus to arterial wall, and therefore perfectly adapted to prevent natural adverse effects of healing process.



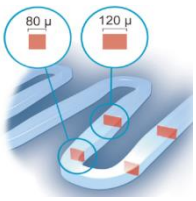


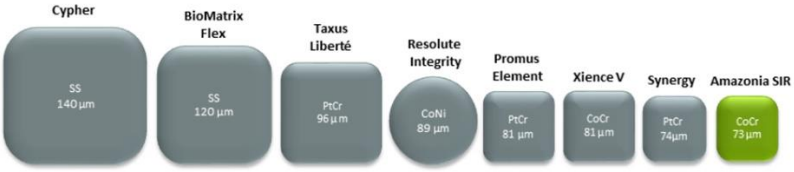
Stent platform

The stent platform is made of cobalt-chromium alloy (L605) that has been successfully used in other implantable medical devices since 1985. The delivery system is a Rapid exchange (RX) system.

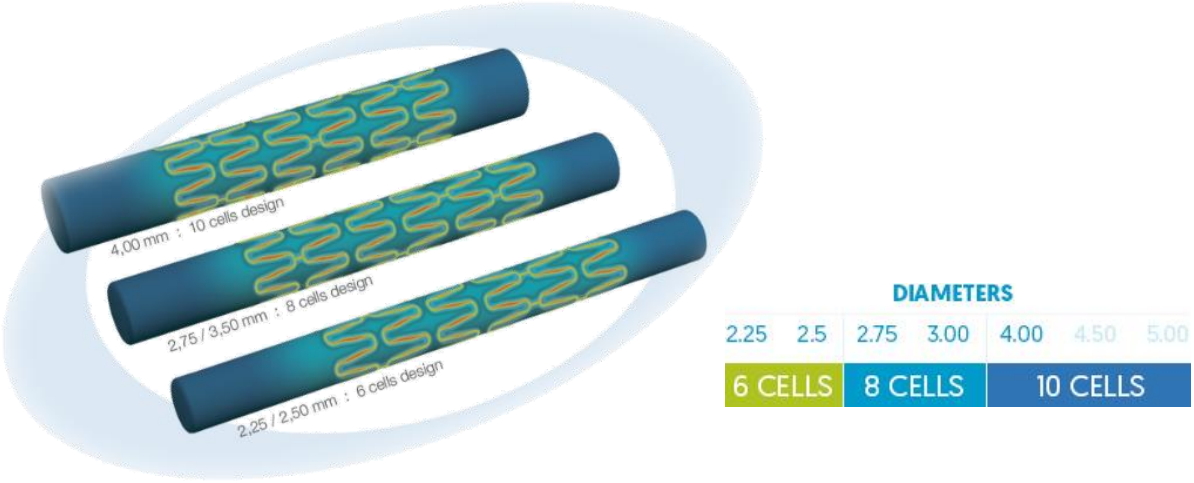
Amazonia SIR has a unique thin strut design that allows more flexibility, homogenous stent deployment and larger contact surfaces:

- Constant thickness: 73 µm
- Narrow radius width: 80µm
- Larger strut width: 120 µm





Amazonia SIR has an open cell design and has three stent platform designs adapted to vessel diameter with metal/artery ratio of 14%.



3 SIRegistry

AIMS

The purpose of this study is to assess the safety, performance and effectiveness of the Amazonia SIR Sirolimus-Eluting Coronary Stent for the treatment of lesions in native coronary arteries in the real-world clinical practice.

STUDY DESIGN

The SIRegistry is a prospective, worldwide multicenter, internet-based, post-marketing surveillance observational study. The primary endpoint is the rate of Major Adverse Cardiac Events (MACE) evaluated at 12 months. Secondary endpoints include notably: angiographic success, Target Lesion Revascularization (TLR), Target Vessel Revascularization (TVR) and stent thrombosis at 12 months' post-procedure. The patient clinical status is evaluated at 12 months by phone call or a visit at the hospital.

RESULTS

Patients' inclusion started in May 2015 and to date 299 patients were enrolled. The 12 months' clinical follow-up results were available for 172 patients. To date, there was no reported major adverse cardiac event related to the study device. A clinical report will be performed after all patients reached the 12 months' clinical follow-up.

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