Sistema Socio Sanitario
Ospedale Fatebenefratelli e Oftalmico
Ospedale Macedonio Melloni
Regione Lombardia
ASST Fatebenefratelli Sacco

# SPONTANEOUS PROSPECTIVE CLINICAL OBSERVATIONAL TRIAL

# European prospective registry on sirolimus drug-coated balloon

## (thE All-comers Sirolimus-coaTed BallOon eURopeaN rEgistry: the EASTBOURNE REGISTRY)

CONFIDENTIAL

VERSION 1.1

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# PROTOCOL SYNOPSIS

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| Purpose | The purpose of this study is to observe and evaluate the performance of a Sirolimus-eluting Drug-Coated Balloon (SCB) for the treatment of any type of coronary lesions, including native vessel disease and in-stent restenosis. |
| Investigational Device | The SCB that will be used in this study is a semi-compliant polyamide balloon-catheter with low tip profile (0.016"), coated with Sirolimus drug (drug dose of 180μg on 3.0 x 15 mm balloon, drug to excipient ratio of 1:1). |
| Design | This is a prospective, multicenter, spontaneous clinical registry that will enroll real world, all-comer patients at various interventional cardiology sites in Europe. All Patients will have a clinical follow-up at 1, 6, 12 and 24 months. |
| Patient Population and duration of enrollment | We plan to enrol a total number of 800 patients at 20-30 european sites, beginning 07.2016 to 09.2017. |
| Primary endpoint | Target Lesion Revascularization (TLR) at 12 months. |
| Secondary endpoints | MACE (Major Adverse Cardiac Events) as a composite of cardiac death, myocardial infarction (MI) and TLR at 6, 12 and 24 months; any individual element of MACE; procedural success (defined as technical and angiographic success in the absence of MACE during hospitalization). |

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| Patients | All patients with a clinical indication to PCI. |
| Inclusion Criteria | • Age ≥ 18 years;<br>• Patients with symptomatic coronary artery disease (including patients with chronic stable angina, silent ischemia, and acute coronary syndromes) with clinical indication to PCI. |
| Exclusion Criteria | Patients with one or more of the following criteria:<br>• Patients with known (and untreatable) hypersensitivity or contraindication to Aspirin, Heparin, Clopidogrel, Prasugrel, Ticagrelor, Sirolimus or contrast media, which cannot be adequately pre-medicated.<br>• Patients participating in another clinical evaluation.<br>• Target lesion/vessel with any of the following characteristics:<br>o successful pre-dilatation not performed in the target lesion, or not efficacious (residual stenosis >50%);<br>o severe calcification of the target vessel, also proximal to the lesion;<br>o highly tortuous lesions which can impair access of device to treatment site.<br>• Visible thrombus at lesion which is not treatable with aspiration. |

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| Methodology | Patients will be followed after hospital discharge for up to 24 months: cardiac visits or phone calls will be scheduled at 1, 6, 12 and 24 months. |