Study Title: DynamX Bioadaptor Hong Kong Registry

NCT Number: NCT04483791

Protocol Number: ELX-CL-2001

Version 2.0, 7 December 2020

Title	**A Non-Randomized, Clinical Registry of the DynamX Novolimus Eluting Coronary Bioadaptor System in the Treatment of Patients with *de novo* Native Coronary Artery Lesions** "DynamX Hong Kong Registry"
Objective	To confirm the clinical performance of the DynamX™ Novolimus Eluting Coronary Bioadaptor System with regard to acute device success defined as a < 30% residual stenosis of the target site using the assigned device without the need for other non-study stents or adjunctive devices (e.g. rotablator or atherectomy) and to collect longer-term clinical data at 1, 6 and 12 Months.
Study design	A prospective, non-randomized, multicenter registry. Subjects with up to two *de novo* native coronary artery lesions measuring between 2.25 and 3.5 mm in diameter and ≤ 34 mm in length receiving the DynamX Novolimus Eluting Coronary Bioadaptor System (CSS), with primary, interim clinical follow-up via clinic visit at 1 month. Follow-up will continue at 6, and 12 months. to capture cardiovascular related hospitalizations related to the study device.
Enrollment/ Number of Sites	Enrollment of up to 50 subjects at approximately four centers in Hong Kong
Study Devices	DynamX® Novolimus Eluting Coronary Bioadaptor System
Key Endpoints:	**Performance:** Acute Device Success: attainment of final result of < 30% residual stenosis using the DynamX bioadaptor with standard pre-dilatation and post-dilatation (if applicable) catheters **Clinical parameters to be evaluated** • Device Oriented Clinical Endpoint (DOCE) at 1, 6, and 12 Months, defined as the composite of cardiovascular death, target vessel myocardial infarction (TV-MI)*, or clinically-driven target lesion revascularization (ID-TLR). • Death at 1, 6 and 12 Months; Cardiac and non-cardiac • Myocardial infarction at 1, 6 and 12 Months • Clinically-indicated Target Lesion and Target Vessel Revascularization (TLR and TVR) at 1, 6 and 12 Months • Device Thrombosis at 1, 6 and 12 Months *Endpoints will be defined as per the Academic Research Consortium (ARC-2) criteria*

Key Inclusion Criteria	Candidates for this study must meet all of the following criteria: 1. Subject age ≥ 18 and ≤ 80 years 2. Subject (or legal guardian) understands the trial requirements and treatment procedures and provides written informed consent prior to any trial-specific tests or treatment 3. Indication for a percutaneous intervention with stent implantation in native epicardial arteries including patients with stable coronary artery disease and acute coronary syndromes (non-ST-elevated myocardial infarction) 4. Vessel diameter (2.25-3.5 mm) and lesions length ≤ 34 mm suitable for implantation using a single stent per lesion 5. All lesions requiring PCI should be amendable for implantation with the study stent. 6. Successful pre-dilatation of the first lesion defined as no waist in the inflated pre-dilatation balloon using two orthogonal views using a pre-dilatation balloon diameter size ranging from the reference vessel diameter to 0.25 mm to 0.5 mm smaller than the reference vessel diameter, and a residual diameter stenosis prior to study device implantation by visual estimate being < 35%
Key Exclusion Criteria	Candidates will be ineligible for enrollment in the study if any of the following conditions apply: 1. Target lesion / vessel specific a. Lesions in the left main b. Venous or arterial bypass grafts c. In-stent restenosis d. Chronic total occlusion e. Ostial lesions (< 3 mm from the ostium of the RCA, LAD or Cx) f. Stent implanted < 10 mm from the target lesion in the previous 30 days g. Lesion requiring rotablation or atherectomy because of, but not limited to, severe calcification h. Bifurcation lesions requiring a planned 2 or more stent technique 2. Patient specific: a. STEMI b. Acute myocardial infarction with Killip Class III and IV c. Known LVEF < 30% d. Life expectancy < 1 year e. Patients on renal dialysis or known GFR < 30 ml/min.

	3. Planned surgery necessitating interruption of dual antiplatelet therapy within the first 6 months. 4. Known intolerance to components of the investigational product or medication required (e.g. intolerance to concomitant anticoagulation or antiplatelet therapy) 5. Subject is receiving or will require chronic anticoagulation therapy (e.g. coumadin, dabigatran, apixaban, rivaroxaban, edoxaban or low molecular weight heparin) 6. Subject is currently participating in another clinical trial with an investigational drug or device that has not yet completed its primary endpoint 7. Known pregnancy or breastfeeding 8. Subject is in the opinion of the Investigator or designee, unable to comply with the requirements of the study protocol or is unsuitable for the study for any reason
Statistical Analysis	This registry was designed to confirm the performance of the DynamX Novolimus Eluting Coronary Bioadaptor System with regards to the residual risks of lesion access and acute device implantation through visually-assessed angiographic endpoints and physician feedback and demonstrate that these characteristics are acceptable. Data for all categorical endpoints was summarized with patient counts and percentages. While this registry is not powered to determine rare events, the sample size is sufficient to determine device related performance issues. Observational comparisons were provided from the DynamX Mechanistic study.
Sponsor	Elixir Medical Corporation 920 N McCarthy Blvd, Suite 100 Milpitas, CA 95035 USA