STUDY TITLE	**CONSEQUENT ALL COMERS - Clinical PMCF on Peripheral Arteries treated with SeQuent® Please OTW Paclitaxel Coated Balloon Catheter in an All Comer Patient Population**
STUDY POPULATION	**Patient with Peripheral Artery Disease (PAD)**
PRINCIPAL INVESTIGATOR	Dr. Shaiful Azmi Yahaya
STUDY COORDINATOR	Salizah Selamat Contact number : 03 – 2617 8200 ext 3132
START DATE	26 Apr 2016
END DATE	31 Dec 2016
INCLUSION	a. <u>Inclusion Criteria : Patient Related</u> • Willingness to treat the target lesion according to the DRB only concept • Patient in Rutherford classes 2 through 5 • Patient eligible for peripheral revascularization by means of PTA • Patient must be age 18 years or more • Patient who are mentally and linguistically able to understand the aim of the study and to show sufficient compliance in following the study protocol • Patients must agree to undergo at least the 1 year clinical follow-up • Patient is able to verbally acknowledge an understanding of the associated risks, benefit, and treatment alternatives to therapeutic option of this study, e.g. balloon angioplasty by means of the paclitaxel-eluting PTA-balloon catheter or other suitable devices. The patients, by providing their informed consent, agree to these risks and benefits as stated in the patient informed consent document. b. <u>Inclusion Criteria : Lesion Related</u> • Peripheral lesions in peripheral arteries with reference vessel diameters between 1.5 or more and 8.0 mm or less, lesion length 2cm or more and 27cm or more as angiographically documented. Lesion separated by less than 2 cm are considered as one lesion • Diameter stenosis pre-procedure must be 70% or more • Vessels must have adequate run-off with at least one vessel to the foot

EXCLUSION	a. <u>Exclusion Criteria : Patient Related</u> • Patient with Rutherford Class 6 • Patients with an expected life span of less than 24 months • Patient with bleeding diathesis in whom anticoagulant or anti-platelet medication contraindicated • Patient who had a cerebral stroke less than 6 months prior to the procedure • Patient participates in other clinical trials involving any investigational device or that interfere with the effects to be studied in this trial • Untreated hyperthyroidism • Patient has presence or history of several renal failure (GFR less than 30ml/min) therefore not eligible for angiography. Patient's serum creatinine level must documented • Post transplantation of any organ or immune suppressive medication • Other disease to jeopardize follow up (e.g malignoma) • Addiction to any drug or to alcohol (WHO definition) • Patient with any type of surgery during the week preceding the intervention procedure • Conditions which prevent the intake of the DAPT for one month b. <u>Exclusion Criteria : Lesion Related</u> • Strongly calcified lesions with circumferential presence of calcification and a lesion length of more than 4cm • Inflow lesion (proximal to the study lesion) with flow limitation not being successfully treated prior to the study lesion c. <u>Exclusion Criteria : Concomitant Medication Related</u> • Patient has leucopenia (leukocyte count less than 10^9 / liter for more than 3 days) • Patient has neutropenia (ANC less than 1000 neutrophils/mm^3 for more than 3 days) • Patient has a history of peptic ulcer or gastric/intestinal bleeding during the past 6 months • Patient has a history of thrombocytopenia (less than 100,000 platelet/mm^3)