

STUDY TITLE	BIOLUX P-III REGISTRY : BIOTRONIK - A prospective, international, multi-centre, post-market all-comers registry to assess the clinical performance of the Paseo-18 Lux Paclitaxel releasing balloon catheter in infraginal arteries -III
STUDY POPULATION	Patient with Peripheral Artery Disease (lower limb)
PRINCIPAL INVESTIGATOR	Dr. Shaiful Azmi Yahaya
STUDY COORDINATOR	Salizah Selamat Contact number : 03 – 2617 8200 ext 3132
START DATE	21 Oct 2015
END DATE	Dec 2016
INCLUSION	<ul style="list-style-type: none"> • Age 18 years or more or minimum age as required by local regulations • Subject must be willing to sign a Patient Data Release Form (PDRF) or Patient Informed Consent (PIC) where applicable • Lesion(s) in the infrainguinal arteries suitable for endovascular treatment treated with or scheduled to be treated with the Paseo-18 Lux drug releasing balloon
EXCLUSION	<ul style="list-style-type: none"> • Life expectancy 1 year or less • Subject is currently participating in another investigational drug or device study that has not reached its primary endpoint yet • Subject is pregnant or planning to become pregnant during the course of the study • Failure to successfully cross the target lesion with a guide wire (successful crossing means tip of the guide wire distal to the target lesion in the absence of flow limiting dissections or perforations)