BIO-RESORT Statistical Analysis Plan

Baseline characteristics will be reported as mean ± SD or as percentage for categorical and dichotomous variables. If variables are not normally distributed, values are reported as median with corresponding interquartile range. The primary endpoint Target Vessel Failure (TVF) at 12 months will be analyzed by the logrank test by comparing the time to the primary endpoint using the Kaplan-Meier method for the two primary comparisons (Synergy versus Resolute Integrity and Orsiro versus Resolute Integrity). Non-inferiority will be achieved if the upper limit of the one-sided 97.5% confidence interval of the absolute risk difference is less than the non-inferiority margin. After non-inferiority has been established, superiority testing will be performed as well as calculation of 2-sided 95% confidence intervals. The primary analyses will be performed based on the principles of intention-to-treat. We will calculate hazard ratios using Cox proportional hazards regression analysis. To account for intra-patient correlation (due to inter-lesion dependence), we will perform an additional lesion-based analysis using the generalized estimating equation method.

Pre-specified subgroup analyses will be performed for, but will not be limited to, diabetes mellitus, age, gender, recent MI, in-stent restenosis, known renal insufficiency, bifurcation lesion, left main stenting, bypass graft lesion treated, multivessel stenting, number of implanted stents, lesion length, small vessels, and number of treated lesions in which the primary and secondary endpoints will be analyzed. The subgroup analyses will be performed to assess consistency of treatment effect across different subsets. P values < 0.05 will be considered statistically significant, except for the primary analyses, as outlined above.