1.1.1 *Statistical Analysis:*

1.1.1.1 Continuous data

Prior to any analysis of continuous data histogram analysis was performed to establish the distribution. If the data appeared normally distributed the Kolmogorov statistic or Shapiro Wilk statistic was utilized to confirm this, with a P value > 0.05 indicating normality.

Normally distributed data was described as mean (95% confidence interval) or mean (standard deviation). For data not normally distributed it was described as median (interquartile range).

Hypothesis testing was performed comparing groups as per distribution and whether it was paired or unpaired. N.B. paired data is that which is before and after in the same patient, whilst unpaired data is that from different patients.

The P value represents the probability of the null hypothesis being true[317] (i.e. no difference between the data). P values are quoted to 3 decimal places with values of less than 0.05 being considered significant i.e. suggesting rejection of the null hypothesis.

The comparison of baseline characteristics between the control and active groups i.e. intergroup analysis was performed using the unpaired student T test for normally distributed data and Mann Whitney U test for non-normally distributed data.

1.1.1.2 Categorical data

Simple categorical data is presented as percentages. The primary test utilized was Pearson's Chi squared test. If more than 20% of the expected frequencies were <5 or if any were <1 then the Fisher's exact test was utilized.

1.1.1.3 Linear Regression analysis

Secondary analysis of covariates determined to be significant predictor of device failure on univariable analysis was carried out using linear regression analysis.

1.1.2 *Withdrawals and dropouts:*

During the study, treatment may be discontinued for many reasons such as an adverse event that could interfere with the subject's evaluation, or simply upon the subject's request to discontinue for any reason. Concurrent medical events that do not interfere with scheduled testing, and that are judged by the Investigator to not influence the outcome measures will not disqualify a subject from continuing in the study. If a subject is withdrawn from the study because of an AE, treatment discontinuation must be explained on the CRF.

Patients will be advised that they are free to withdraw from the study at any time for any reason or, if necessary, the Investigator may withdraw a subject from the study to protect the subject's health. The Investigator may withdraw a subject from the study if it is considered that the scientific, and therefore, ethical standards of the study are compromised. Patients may also be withdrawn for not complying with study procedures. The type and timing of the withdrawal for withdrawal will be fully recorded on the CRF.

1.1.3 *Trial Exit:*

Participants will exit the trial completely if:

- they have been in the trial for 30 days following randomisation and completed follow up at 3 months and 1 year.
- they request to/ are unable to continue being followed-up
- they suffer an adverse event/ reaction such that they cannot continue
- they die

1.1.4 *Overall timescale for the study:*

Recruitment will begin as soon as all necessary approvals have been obtained (Ethics, MHRA and Trust R+D). Recruitment will run for approximately 12-18months or until an adequate sample size is reached. Individual participants are involved in the trial for 30 days as per the aforementioned Centre for Disease Control definition of an SSI in non-implant surgery.