

Cover Letter:

All enclosed below documents are part of the clinical trial NCT03536819

**Study Name: Radio-frequency rejuvenation for pelvic floor and vagina**

**Protocol No.:** DO607404A

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I. Data analysis.

A. Analysis Sets

1. Safety Analysis Set

*a) The safety analysis set will include all subjects using Votiva procedures at least a single time.*

2. Performance Analysis Set

*a) Performance analysis set will consist of all subjects providing at least one post treatment performance measurement.*

3. Treatment of Missing Values

*a) Only observed data will be used; i.e. missing data will not be imputed.*

B. Statistical Analysis

1. Means, and standard deviations for each characteristic will be calculated. Paired sample t-test will be computed to assess changes in before treatment and follow-up scores. Statistical significance will be calculated and two-tail significance level of 0.05 will be used. All analyses will be conducted using IBM SPSS 21.0.