STATISTICAL ANALYSIS PLAN

Protocol Number: CL 04897

Study Title: EvaluatiOn of Uterine Patency following Sonography-guided TranscErvical AblatioN of Fibroids (OPEN)

Development Phase of Study: Post-market

[redacted]

Statistical Analysis Plan based on Protocol Version: 13 July 2017

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Revisions to the Statistical Analysis Plan described herein must be approved through a formal written amendment with the exception of minor editorial changes to tables, figures, or listing shells, and any necessary textual clarifications for programmers that do not affect the stated analysis variables, study endpoints, or statistical methods.

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APPENDICES

1. LIST OF ABBREVIATIONS

AE(s)	Adverse Event(s)
ADE	Adverse Device Effect
eCRF(s)	Electronic Case Report Form(s)
DMP	Data Management Plan
e.g.	*exempli gratia* (for example)
ESH	European Society of Hysteroscopy
EQ-5D	EuroQuol 5 dimension (patient questionnaire)
FAS	Full Analysis Set
FDA	Food and Drug Administration
FIGO	International Federation of Gynecology and Obstetrics
HMB	Heavy Menstrual Bleeding
IUUS	Intrauterine Ultrasound
ICH	International Conference on Harmonization
N	Number (sample size)
OTE	Overall Treatment Effect
SADE	Serious Adverse Device Effect
SAE(s)	Serious Adverse Event(s)
SAS®	Statistical Analysis System (SAS® Institute Inc., Cary, NC)
SD	Standard Deviation
UADE	Unanticipated Adverse Device Effect

2. INTRODUCTION

The Sonata System combines intrauterine ultrasound (IUUS) with radiofrequency (RF) ablation in a single handpiece, enabling transcervical visualization and ablation of uterine fibroids without incisions. Sonata is intended to provide focal treatment of symptomatic fibroids responsible for heavy menstrual bleeding (HMB). This Statistical Analysis Plan (SAP) describes the analytical methods to be used to assess the safety and effectiveness of the Sonata System in the treatment of symptomatic uterine fibroids.

3. STUDY OBJECTIVES

The objective of this study is to document the presence or absence of newly formed intrauterine adhesions after treatment with the Sonata System when used in women with submucous and/or transmural fibroids in accordance with product labeling.

4. INVESTIGATIONAL PLAN

4.1 Overall Study Design

The study is designed as a post-market prospective, multicenter, single-arm cohort study.

4.1.1 Schedule of Screening and Study Assessments

Table 1: Schedule of Screening and Study Assessments

Assessment	Consent	Baseline and Treatment		Follow up
		Baseline	Treatment	6 wks
Informed Consent	X			
Demographics		X		
Transvaginal sonography		X[1]		
Hysteroscopic assessment of uterine cavity		X[1]		X
Sonata Treatment & Procedure Assessments			X[1]	
Adverse events			X	X
EQ-5D		X		X
OTE and Subject Satisfaction				X
Return to normal daily activity/Treatment Recovery Questionnaire				X
Pregnancy and pregnancy outcome / surgical reintervention*				X

* If subject undergoes hysterectomy, operative and pathology reports shall be forwarded to study sponsor

[1] As per routine medical care

4.2 Selection of Study Population

4.2.1 Inclusion Criteria

1) Have selected Sonata for treatment of fibroids in the presence of heavy menstrual bleeding
2) Presence of at least one submucous myoma (type 1, type 2) or transmural fibroid (type 2-5)
3) Are ≥ 18 years of age at the time of enrollment
4) Willing and able to read, understand, and sign the informed consent form and to adhere to all study follow-up requirements

4.2.2 Exclusion Criteria

1) Preexisting adhesions within the endometrial cavity as indicated by an ESH score ≥ I as determined by the investigator
2) One or more Type 0 fibroids and/or endometrial polyps of any size
3) Any reason for which, in the opinion of the Investigator, the individual study patient is not appropriate or suitable for participation in this study

4.3 Treatments

The Sonata System is a CE-marked device and is used within its intended purpose in this study. The treatment shall be performed in accordance with the Sonata System Operator's Manual. Sponsor representatives may assist the Investigator (generally one to three individuals) and may be present during the procedure to provide equipment support if needed as well as for proctoring and general observation.

4.4 Data Management

Data collected for the study will be entered into a web-based system through electronic Case Report Forms (eCRFs) by each study site. The Electronic Data Capture (EDC) system maintains a complete electronic audit trail. The design and specification of eCRFs as well as edit checks will be in accordance with the study requirements. For statistical analysis, data stored in the central database will be exported to SAS® files (SAS Institute Inc, Cary, NC, USA). The data extract from the final locked database will be used to generate the final clinical study report.

Prior to database lock, the following steps must be completed: data entry or transferring as required per protocol, source verification, query resolution, data review by clinical data managers and final sign-off by site principal investigators.

4.5 Efficacy and Safety Variables

4.5.1 Primary Efficacy Variables

4.5.1.1 Incidence of Newly Formed Intrauterine Synechiae at Six Weeks

Incidence of newly formed intrauterine synechiae at six weeks will be assessed via diagnostic hysteroscopy, with any adhesions classified per the European Society of Hysteroscopy (ESH) scoring system (see Appendix D). Diagnostic hysteroscopy will be captured on digital video and forwarded to two independent readers. In the event of a disagreement in ESH score between the readers, a third independent reader will perform a tiebreaker review.

4.5.1.2 Surgical Reintervention

Subjects will be asked to indicate whether any of their adverse events required a surgery or procedure. The rate of surgical reintervention due to treatment failure will be evaluated throughout all assessment timepoints. Surgical reintervention for the treatment of HMB includes the following procedures:

a) Hysterectomy (abdominal, vaginal, laparoscopic)

b) Myomectomy (abdominal, vaginal, laparoscopic, hysteroscopic)

c) Uterine artery embolization

d) Magnetic resonance-guided focused ultrasound (MRgFUS) or similar focused ultrasound treatment

e) Endometrial ablation (nonresectoscopic, hysteroscopic)

4.5.2 Secondary Efficacy Variables

4.5.2.1 Overall Treatment Effect (OTE)

Subjects will be asked to indicate whether their uterine fibroid symptoms have improved, remained the same, or worsened. If the subject indicates that her symptoms have improved, she will be asked to rate the degree of improvement on a 7-point scale from “almost the same, hardly better at all” (1) to “a very great deal better” (7). If the subject indicates that her symptoms worsened, she will be asked to rate the degree of worsening on a 7- point scale from “almost the same, hardly worse at all” (-1) to “A very great deal worse” (-7). A copy of the questionnaire is included as Appendix C.

4.5.2.2 Subject Satisfaction

Subjects will be asked to rate their satisfaction with the treatment, with responses based on a 6-point Likert scale ranging from "very satisfied" to "very dissatisfied". They will also be asked if they would recommend the treatment to a friend with the same health problems using a 4-point scale from "definitely yes" to "definitely not".

4.5.3 Procedure Variables

Procedure information will be captured within the eCRF. The device insertion and removal times will be collected to facilitate the calculation of procedure time. Additionally, the time and date of discharge will be collected. The anesthesia and procedure-related medications, and number and size of each fibroid treated will also be captured, along with the number of ablations for each fibroid.

4.5.4 Safety Variables

4.5.4.1 Adverse Events

Adverse events will be reported and classified by the Investigator using the specific medical diagnosis, or using signs, symptoms or abnormal laboratory values if no medical diagnosis can be identified.

4.5.4.1.1 Adverse Event Definitions

A. **Adverse Event (AE)** - Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including a clinically significant abnormal laboratory finding) in subjects, users or other persons whether or not related to the Sonata System.

1) This includes events related to the procedures involved.
2) For users or other persons this is restricted to events related to the Sonata System or it's procedure
3) Increase in frequency or severity of symptoms relative to baseline are considered an adverse event if they are not related to a measured endpoint

NOTE 1: An elective surgical reintervention for HMB is not considered an adverse event.

NOTE 2: Presence of adhesions discovered during follow-up are not considered as an adverse event

NOTE 3: Inpatient admission does not constitute hospitalization for the purposes of this protocol as long as there are no reported adverse events associated with the stay

B. **Serious Adverse Event (SAE)** – Adverse Event that led to

1) Death
2) A serious deterioration in the health of the subject that either resulted in:
    - A life-threatening illness or injury, or
    - A permanent impairment of a body structure or a body function, or
    - An in-patient hospitalization, or prolongation of existing hospitalization, of more than 24 hours, or
    - A medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function.
3) Fetal distress, fetal death or congenital abnormality or birth defect

NOTE 1: A planned hospitalization for a pre-existing condition, or a procedure required by the clinical investigational plan, without a serious deterioration in health, is not considered to be a serious adverse event.

NOTE 2: If recovery time from treatment with the Sonata System is no longer than expected and site scheduling prevents same-day discharge, overnight stay is not considered prolonged

C. **Adverse Device Effect (ADE)** - Adverse Event related to the use of a medical device. This includes:

1) Any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the installation, the operation, or any malfunction of the Sonata System.
2) This definition includes any event that is a result of a use error or intentional misuse.

D. **Device Deficiency**

As this is a clinical trial utilizing a CE-marked device, device eficiencies ("incidents") are collected and reported by Gynesonics, Inc. according to Gynesonics' Complaint Handling system and per MEDDEV 2.12.1.

If the device deficiency involves an adverse event category as described in this protocol, the investigator shall notify the Sponsor by completing the adverse event or death case report form as applicable and must provide the Sponsor with all necessary documentation needed. If the device deficiency does not involve a reportable adverse event per this protocol, the investigator should notify the Gynesonics, Inc. Complaint Coordinator by emailing the information about the device deficiency to: regulatory@gynesonics.com.

E. **Serious Adverse Device Effect (SADE) -** Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

F. **Unanticipated Serious Adverse Device Effect (USADE) -** Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

As this clinical trial is conducted according to the Sonata System's approved CE mark labeling, within its approved indications, and in accordance with its instructions for use, the Investigator and sponsor will follow the Medical Device Vigilance Guidelines (per MEDDEV 2.12.1) and report adverse events according to that guideline.

G. **Anticipated** - An effect which by its nature, incidence, severity or outcome has been previously identified in the risk analysis

4.5.4.1.2 Adverse Event Evaluations

Each adverse event in the study will be evaluated by the investigator as to its severity, its relationship to the study device and to the procedure, and whether it was anticipated in the investigational plan. The distinction between an AE, an SAE, and a UADE will be made according to the definitions given above. Gynesonics is responsible for the classification of adverse events. In case of disagreements in which the investigator's evaluation is that the event is more serious and/or more related, both opinions will be included in adverse event reports.

4.5.4.1.3 Relatedness

The determination of the level of relatedness of the adverse event to the Sonata device or Sonata procedure will be made according to the definitions below. Adverse events considered to be "Related", "Possibly Related", or "Not Related" to the Sonata System will be classified as an ADE or an SADE for purposes of statistical analysis.

1) Related: The adverse event was directly and clearly related to the Sonata System or procedure.
2) Possibly Related: The adverse event may have been related to Sonata System or procedure, but an alternative cause is equally likely.
3) Not Related: The adverse event was not related to the Sonata System or procedure.

Complications of procedures in the study are considered not related if the said procedures would have been applied to the subject also in the absence of the study device use/application.

4.5.4.2 EuroQOL EQ-5D

The EQ-5D should be completed during the subject's baseline and six week follow-up visit. It should be completed based solely on symptoms from that cycle. If the subject has become amenorrheic, the EQ-5D may be completed at any time during the follow-up visit window. A copy of the questionnaire is included as Appendix B.

4.5.4.3 Treatment Recovery Questionnaire

Subjects will be given a Treatment Recovery Diary at discharge and asked to complete questions daily regarding return to normal activities for the first two weeks post-procedure. A copy of the questionnaire is included as Appendix A.

4.6 Statistical Methods

All statistical processing will be performed using SAS® unless otherwise stated.

Continuous variables will be summarized descriptively using number of subjects (n), mean, standard deviation (SD), minimum, median, and maximum. Categorical variables will be summarized descriptively using frequency counts and percentages.

Analyses presented for the Per-Protocol (PP) will be considered primary.

4.6.1 Analysis Populations

The safety population will be comprised of subjects who received study treatment.

The Per-Protocol population (PP) will be comprised of subjects in the safety population who have a post baseline assessment, an evaluable hysteroscopy at Baseline and Week 6 follow-up and completed the Week 6 follow-up visit.

4.6.2 Subject Disposition

The number of subjects included in each analysis population (PP and Safety) will be summarized, as well as the reasons for exclusion from the population. The number of subjects completed and discontinued (including the reasons for discontinuation) will be summarized.

4.6.3 Demographic and Baseline Characteristics

Subject demographic and baseline characteristics will be summarized descriptively for the PP and safety populations. Demographic and baseline variables will include variables such as age, height, weight and BMI. OB-GYN history variables will also be summarized. Demographic and baseline variables as well as OB-GYN history variables will be summarized using descriptive statistics.

4.6.4 Efficacy Analyses

Efficacy evaluations will be summarized descriptively, by visit.

4.6.4.1 Primary Efficacy Analysis

Final Outcome will be presented using frequency counts and percentages for No New Adhesions at Week 6 and Adhesions at Week 6. Specifically, Final Outcome will be determined based on agreement in hysteroscopy evaluation between 2 out of the 3 Independent Readers. The ESH score will also be summarized using descriptive statistics for baseline (both Investigator and Independent Reader) and the Week 6 visit (Independent Reader only). The Final Outcome assessment will be done for both the Safety and Per Protocol populations. In either population:

- For subjects whose final 6-week hysteroscopy determination per agreement by two out of three Independent Readers shows Adhesion(s):
    - Final Outcome is **New Adhesion** if the final baseline hysteroscopy determination per agreement by two out of three Independent Readers showed No Adhesion.
    - Final Outcome is **Undetermined** if the final baseline hysteroscopy determination per agreement by two out of three Independent Readers showed Adhesion.
    - Final Outcome is **Undetermined** if there were no evaluable hysteroscopy at baseline.
- For subjects whose final 6-week hysteroscopy determination per agreement by two out of three Independent Readers shows presence of No Adhesion(s):
    - Final Outcome is **No New Adhesion.**

In addition, a reader agreement analysis will be presented using frequency counts and percentages for the Baseline and the Week 6 visits.

4.6.4.2 Other Efficacy Analysis

4.6.4.2.1 Overall Treatment Effect (OTE)

OTE will be summarized using descriptive statistics.

4.6.4.2.2 Subject Satisfaction

Subject Satisfaction will be summarized using descriptive statistics.

4.6.5 Procedure Summaries

The following procedure related information will be summarized using descriptive statistics:

- LOS (start of procedure to discharge)
- Time admission to discharge
- Procedure time (time of device insertion to removal)
- Patient Side (left, right, midline)
- Location (anterior, posterior, midline)
- Location (fundal, body, LUS, cornual, other)
- Fibroid type
- FIGO type
- Size of fibroids treated (visualized and ablated)
- Number of fibroids treated
- Number of fibroids per subject
- Number of ablations per fibroid
- Number of ablations per subject
- Number of ablated fibroids per subject

4.6.6 Transvaginal Ultrasound Summaries

The following transvaginal ultrasound related information will be summarized using descriptive statistics:

- Location (anterior, posterior, midline)
- Location (fundal, body, LUS, cornual, other)
- Patient Side (left, right, midline)
- Fibroid type
- FIGO type
- Maximum FIGO Type per subject
- Size of fibroids
- Number of fibroids
- Number of fibroids per subject

4.6.7 Safety Analyses

4.6.7.1 Adverse Events

Procedure safety will be assessed by recording all AEs that occur on the day of the treatment procedure. Longer-term safety will be assessed by recording at the follow-up visit any untoward medical occurrence since baseline. Each AE will be assessed for relationship to study device and/or procedure. In addition to evaluating procedural and longer-term safety, subjects who become pregnant after the procedure will be asked to report any pregnancy complications.

Descriptions of AEs will include the date of onset, the date the AE resolved, stabilized, or returned to baseline, and the outcome. All reported AEs will be summarized by the number of subjects reporting AEs, seriousness, and relationship to the Sonata System device and/or procedure. Summaries will also be presented for device-related AEs, and procedure-related AEs.

AEs will be summarized both by subject incidence rate and event incidence rate. In addition, AEs will be summarized by relationship to the Sonata System procedure and/or device, such that each subject will be counted only once for each AE by using the AE with the greatest relationship within each category. The sponsor is responsible for classifications of adverse events. Both investigator reported and sponsor evaluated classifications will be summarized.

4.6.7.2 EuroQOL EQ-5D

The EuroQOL EQ-5D will be summarized by visit using descriptive statistics.

4.6.7.3 Treatment Recovery Diary

The treatment recovery diary will be used to calculate the following parameters in days:

- Return to Normal Daily Activities
- Return to Normal Diet
- Return to Normal Sleep
- Return to Normal Urinary Function
- Return to Normal Bowel Movement

Each of these parameters will be summarized using descriptive statistics.

4.6.8 Determination of Sample Size

The sample size for this study is up to 60 subjects. This is an exploratory study and is not intended to be statistically powered.

4.6.9 Statistical/Analytical Issues

4.6.9.1 Adjustments for Covariates

Not applicable to this study.

4.6.9.2 Handling of Dropouts or Missing Data

Unless otherwise specified, missing data will not be imputed for analyses.

4.6.9.3 Interim Analyses and Data Monitoring

No interim analyses are planned.

4.6.9.4 Multicenter Studies

The clinical study will be conducted under a common protocol for each investigational site with the intention of pooling the data for analysis. Every effort will be made to promote consistency in study execution at each study site.

4.6.9.5 Multiple Comparisons/Multiplicity

No adjustments for multiple comparisons or multiplicity will be made.

4.6.9.6 Examination of Subgroups

Not applicable to this study.

4.7 Changes in the Conduct of the Study or Planned Analyses

No changes to planned analyses.

Appendix A: Treatment Recovery Diary

OPEN STUDY
EvaluatiOn of Uterine PatENcy following
Sonography-guided Transcervical Ablation of Fibroids

Subject ID: | | | - | | |

Treatment Recovery Questionnaire
Post-Treatment Week 1

The attached questionnaire includes questions about your ability to perform your usual activities.

Please answer these questions every night before going to bed for 14 days following your treatment, and consider the previous 24 hours when answering the questions for each day. Try to answer these questions at the same time every night.

Treatment Day is "Day 0": _____ / _____ / _____ *(mm/dd/yy)*

	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
1. DATE *(mm/dd/yy (ie.,03/24/14))*							
2. Were you able to return to normal daily activities today?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
SPECIFIC ACTIVITIES							
3. Have you returned to work?	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable
4. Are you able to perform usual household tasks?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
5. Are you able to drive a car today (even if you did not)?	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable
6. Are you able to participate in your usual recreational activities?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
7. Are you able to lift or carry as normal?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
8. Are you able to eat your regular diet?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
9. Are you able to sleep normally?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
10. Are you able to urinate normally?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
11. Are you able to have normal bowel movements?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N

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EvaluatiOn of Uterine PatENcy following
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Subject ID: | | | - | | |

Treatment Recovery Questionnaire
Post-Treatment Week 2

Please enter the date of Day 7 below:

	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13
1. DATE *(mm/dd/yy, (ie.,03/31/14))*							
2. Were you able to return to normal daily activities today?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
SPECIFIC ACTIVITIES							
3. Have you returned to work?	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable
4. Are you able to perform usual household tasks?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
5. Are you able to drive a car today (even if you did not)?	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable	Y / N Not applicable
6. Are you able to participate in your usual recreational activities?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
7. Are you able to lift or carry as normal?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
8. Are you able to eat your regular diet?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
9. Are you able to sleep normally?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
10. Are you able to urinate normally?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
11. Are you able to have normal bowel movements?	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N

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EvaluatiOn of Uterine PatENcy following
Sonography-guided Transcervical Ablation of Fibroids

Subject ID: ☐☐ - ☐☐

Treatment Recovery Questionnaire
Post-Treatment

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Sexual Activity

12. Are you currently sexually active?	☐ Yes (proceed to question 13) ☐ No (questionnaire completed)
13. I am sexually active but did not want to resume activity	☐ Yes (questionnaire complete) ☐ No (proceed to 13.a OR 13.b)
13.a ☐ I am sexually active and wanted to resume activity on day _____ after the procedure	
13.b ☐ I am sexually active and wanted to resume activity but am still recovering from the procedure	

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Appendix B: EuroQOL EQ-5D Questionnaire

EQ-5D-3L

OPEN STUDY
EvaluatiOn of Uterine PatENcy following Sonography-guided Transcervical Ablation of Fibroids

Subject ID: ☐☐ - ☐☐

☐ Screening ☐ 6 Weeks

Date: ____/____/____

Complete this questionnaire with consideration of the worst day of your period.

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

Self-Care

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

Pain/Discomfort

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

Anxiety/Depression

I am not anxious or depressed ❑

I am moderately anxious or depressed ❑

I am extremely anxious or depressed ❑

Health Questionnaire English Version for the US
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EQ-5D-3L

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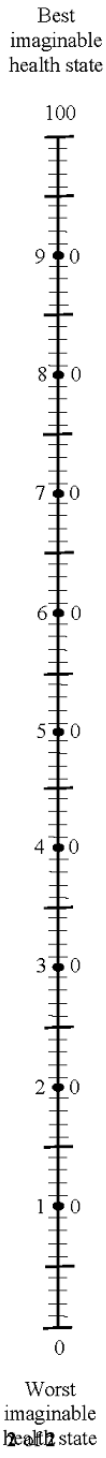
Subject ID: | | | - | | |

☐ Screening ☐ 6 Weeks

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Appendix C: Subject Satisfaction and Overall Treatment Effect

OPEN STUDY
EvaluatiOn of Uterine PatENcy following Sonography-guided Transcervical Ablation of Fibroids

Subject ID: ☐☐ - ☐☐

Overall Treatment Effect and Satisfaction Questionnaire

1. Date you are completing this Questionnaire		_____/_____/_____(mm/dd/yy)
Please indicate if your Fibroid Symptoms are:		
2. ☐ Improved	3. ☐ Same	4. ☐ Worsened
Describe Improvement		**Describe Worsened**
5. ☐ Almost the same, hardly better at all		6. ☐ Almost the same, hardly worse at all
7. ☐ A little better		8. ☐ A little worse
9. ☐ Somewhat better		10. ☐ Somewhat worse
11. ☐ Moderately better		12. ☐ Moderately worse
13. ☐ A good deal better		14. ☐ A good deal worse
15. ☐ A great deal better		16. ☐ A great deal worse
17. ☐ A very great deal better		18. ☐ A very great deal worse
19. Please rate your satisfaction with the Sonata® treatment		☐ Very satisfied ☐ Moderately satisfied ☐ Somewhat satisfied ☐ Somewhat dissatisfied ☐ Moderately dissatisfied ☐ Very dissatisfied

20. Would you recommend the Sonata® treatment to a friend with heavy menstrual bleeding due to fibroids?

☐ Definitely Yes
☐ Probably Yes
☐ Probably No
☐ Definitely No

21. Please explain

_____
_____
_____

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Appendix D: European Society of Hysteroscopy (ESH) Scoring System

Table 3 Classifications of IUA by the European Society for Hysteroscopy (ESH), 1989

Grade	Extent of intrauterine adhesion
I	Thin or filmly adhesion
	Easily ruptured by hysteroscope sheath alone
	Cornual areas normal
II	Singular firm adhesions
	Connecting separate parts of the uterine cavity
	Visualization of both tubal ostia possible
	Cannot be ruptured by hysteroscope sheath alone
IIa	Occluding adhesions only in the region of the internal cervical os
	Upper uterine cavity normal
III	Multiple firm adhesions
	Connecting separate parts of the uterine cavity
	Unilateral obliteration of ostial areas of the tubes
IIIa	Extension scarring of the uterine cavity wall with amenorrhoea or hypomenorrhoea
IIIb	Combination of III and IIIa
IV	Extensive firm adhesion with agglutination of uterine walls
	At least both tubal ostial areas occluded