Raydiant Oximetry, Inc.
KEEPING MOTHERS AND BABIES SAFE DURING CHILDBIRTH

Study Title:

DAISY Uterine Drain

Device Evaluation with Standard Wall Suction

Protocol #CP2400

STUDY SPONSOR

Raydiant Oximetry, Inc.

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Version No.	Version Date	Modifications
V1	10/5/23	N/A- Original Release
V2	4/17/24	Added detail to the sequence of reducing pressures for the Principal Investigator (PI); Update Appendix 1 and 2

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1.0 SUMMARY

The goal of this study is to obtain user feedback while placing and observing the *DAISY* uterine drain with wall suction. This study defines the obstetrical surgeons as "users" and the patients in whom the drain is placed as "participants." Participants are pregnant women who are undergoing cesarean delivery (CD), who have not entered active labor, who have consented to drain placement and who have met all the inclusion/exclusion criteria. Users are staff or fellow obstetrical surgeons who will use the drain and provide the evaluation.

2.0 BACKGROUND AND RATIONALE FOR STUDY

Postpartum hemorrhage (PPH) is the leading cause of maternal mortality worldwide. (D'Alton 2020). It is estimated that 14 million cases of PPH occur each year worldwide (Rath, 2011). In the United States, PPH causes up to 12% of maternal deaths and is the leading cause of death occurring on the day of delivery (ACOG 2017; Butwick 2019; Evensen 2020; Hawkins 2020). According to the American College of Obstetricians and Gynecologists (ACOG), between 54% and 93% of PPH-associated mortality may be preventable while 70-80% of PPH is due to abnormal uterine tone (atony) (ACOG 2017). Atony involves a deficient response to physiological signals that promote uterine contraction and blood vessel compression after delivery. Contraction of the myometrium compresses the blood vessels supplying the placental bed and thereby causes mechanical hemostasis. Uterine atony following CD is a relatively common problem in the non-laboring patient because contraction of the myometrium is almost entirely absent. Restoring uterine tone can be addressed through 1) medication, 2) surgery, or 3) mechanical means. Mechanical restoration of uterine tone includes the use of a tamponade balloon (Hawkins 2020; ACOG 2017, or Bakri® Balloon, Cook Medical, Bloomington, IN). This technique is counterintuitive since it involves outward pressure on the uterus when the actual goal is uterine contraction (D'Alton 2020). Additional devices have employed the use of suction (Jada®, Organon, Inc., Jersey City, NJ).

Post-partum unrecognized uterine hemorrhage due to a closed or narrow cervix that allows blood to collect in a patient undergoing a CD could lead to complications such as dangerously low blood pressure. Providing a conduit for blood to escape via a uterine drain was the basis for developing the *DAISY* Drain. The *DAISY* drain is intended to provide a channel through the cervix for fluid drainage after pelvic surgery. As of September 2023, this device has been deemed "exempt" from the 510(k)-clearance process by the U.S. Food and Drug Administration (FDA). In this study, we wish to use the drain as intended in a small number of subjects but add low-level suction (similar to the Jada device). Briefly, the drain is inserted through the hysterotomy after removal of the placenta and guided down through the cervix and the vagina during the surgery, the distal end of the drain is connected to standard wall suction which establishes a vacuum causing the uterine walls to contract, producing a tamponade of the bleeding vessels and restoring uterine tone. Simultaneously, the suction removes any blood that has collected after closure of the hysterotomy, and the quantity of blood removed can be easily measured by viewing the suction canister. Device evaluation in a small population of appropriate participants is proposed below.

3.0 OBJECTIVES

This is a device evaluation study in 10 women who are undergoing a planned CD or non-emergent CD. Obstetrical-surgeon use of the technology in the operating room provides the Sponsor with the important information on how the intended user population interacts with the drain, ease of placement, and effects of adding suction during a clinical case. Further, the Sponsor wants to test the accuracy of the Instructions for Use document.

4.0 STUDY POPULATION

As described above, this study defines the obstetrical surgeons as "users" and the patients in whom the drain is placed as "participants." The participants consist of women undergoing planned CD for reasons unrelated to this study. We expect to enroll five (5) obstetrical surgeons of various levels of experience who will each place a drain in one to three participants for a total of 10 participants who are qualified based on the Instructions for Use (IFU) *and* who consent to participation. The following contraindications serve as exclusion criteria.

- Known intrauterine or cervical pathology that would interfere with device placement and/or use
- Ongoing intrauterine pregnancy
- Untreated uterine rupture
- Unresolved uterine inversion
- Current cervical cancer
- Current purulent infection of vagina, cervix, or uterus
- Retained products of conception
- Arterial bleeding requiring surgical or angiographic embolization
- Indication for hysterectomy
- Lack of study consent.

5.0 DEVICE DESCRIPTION

The *DAISY* device consists of a soft silicone drainage tube (proximal end) attached to a semi-flexible catheter, inserted through the hysterotomy created at the time of the CD after the uterus is evacuated of products of conception. **(Figure 1)**..

Figure 1

The Drain is threaded through the cervix and the semi-flexible catheter traverses out the vagina where it attaches to suction tubing attached to a canister. **(Figure 2)**

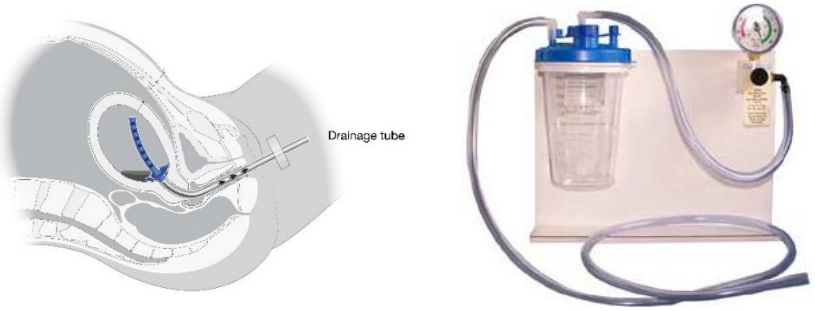

Figure 2

The Drain will be placed on continuous suction according to the IFU for the first two postpartum hours or more if required following evaluation of uterine tone. The drain utilizes standard suction tubing and either wall or portable suction, all readily available on labor and delivery units. The Drain is a closed system that allows clinicians to quantify blood loss and permits direct visual determination of efficacy as evidenced by definitive contraction of the uterus after the uterine incision is repaired.

The *DAISY* drain will be placed intraoperatively after delivery of the placenta, stabilization of the patient, and cleansing of the uterine cavity but prior to closure of the hysterotomy. The *DAISY* drain will be placed through the hysterotomy and threaded through the cervix and vaginal canal, out the introitus, so the distal end is accessible outside of the body (Figure 3).

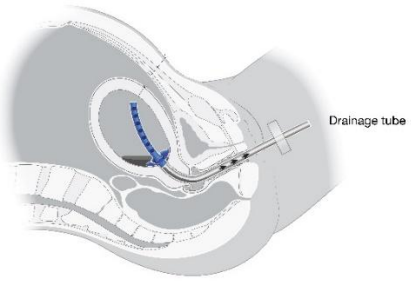

Figure 3

The hysterotomy is then closed taking care not to loop any sutures around the drain. Blood flow through the lumen will be measured by attaching the suction tubing to a fluid collection container (e.g., bag, or calibrated suction cannister). Tubing must be secured to the thighs using a foley catheter securing adhesive to avoid displacement before attaching to the suction canister. For this Protocol, 100mmHg of suction is recommended to induce uterine involution. The *DAISY* drain will remain in place for a minimum of 3 hours while the Participant is in the recovery unit. At the end of 2-hours, the uterus will be evaluated by manual palpation and abdominal ultrasound. The abdominal ultrasound will be performed to document device placement and to assess uterine involution, approximate uterine size and uterine cavity size, presence of intrauterine clots or retained products of conception. Following the ultrasound, the suction is to be reduced to 10mmHg for 5 minutes. After 5 minutes, the investigator will again assess uterine tone and perform another ultrasound. After the second ultrasound, the Daisy is left in place with the suction at 10mmHg for 30 minutes. After 30 minutes, the investigator is to again assess uterine tone manually and perform the third ultrasound.

NOTE: If the uterine cavity is assessed by ultrasound and/or clinically determined to contain clots or products of conception, the device will be removed after discontinuation of suction, the study participant discontinued, and management undertaken per institutional protocol. Thirty minutes before device removal, any suction applied must be discontinued to observe for any additional bleeding. Clinical management of the subject will determine the time for device removal, but the device must be removed within 24 hours of placement. [See "Instructions for Use" provided to the user.]

***DAISY* DRAIN Removal:**

The user who has undergone IFU training will remove the *DAISY* drain after at least two hours post CD based on clinical management. Suction will be discontinued, and the participant observed for 30 minutes before removal. One method of determining if the *DAISY* drain is no longer needed is by checking and documenting uterine tone. If uterine tone has returned to normal as assessed by palpation, the *DAISY* drain may be removed. (Note: If the uterine tone has not returned to normal, the user may choose to leave the drain in place and resume suction.) Upon drain removal, suction is briefly reapplied to collect any blood in the lumen after the 30-minute resting period. **Suction must be discontinued before the drain is removed.** Placing one hand on the abdomen to support the uterus while the other hand slowly withdraws the drain, the person removing the drain will evaluate the ease of drain removal. [See "Instructions for Use" provided to the user.]

6.0 STUDY DESIGN AND METHODOLOGY

This is a prospective, single-arm, device evaluation study of five (5) obstetrical surgeons placing the drain with low-level suction in ten (10) women undergoing elective, non-emergent cesarean delivery.

TEST ENVIRONMENT

The intended test environment is the operating room where the intended users (Obstetrical-Surgeons) are performing a CD. This is a single-center study to be conducted under the approval of the Institutional Review Board associated with the center. Each use of the *DAISY* drain will be documented via user questionnaire and participant case report form (CRF). As this is a device

evaluation study, the study focuses more on the users and less on the participant. However, some participant data will be necessary to collect to comply with the IFU. Further, we intend to assess participants during the post operative visit to ensure that any longer-term adverse effects are detected.

NUMBER OF USERS & PARTIPANTS

In this study, 5 (five) users will place the *DAISY* drain in ten (10) participants do not have any of the contraindications for drain use at the time of the CD. Each user will place the drain at least once but no more than three times. After each obstetrical surgeon uses the *DAISY* drain, they will be asked to complete a questionnaire (Appendix 1).

The *DAISY* drain and Instructions for Use (IFU) will be evaluated qualitatively for the following including:

- ease of drain placement by obstetrician-surgeon
- appropriate size of drain
- appropriate final location of the deployed drain and incidence of improper placement
- ease of drain connection to suction tubing
- ease of drain removal
- perceived effectiveness of suction
- clarity of the IFU

METHODS

User Training:

Minimal product training is necessary other than a review of the IFU. Company personnel will initially observe the insertion and removal procedures and secure feedback post placement and removal to be sure that the IFU is clear and appropriately informative.

Consenting:

The Principal Investigator or research team member may consult a list of eligible patients based on predicted delivery dates. A list of participants who meet/ did not meet eligibility criteria will be maintained in a screening log by the study team. This log will contain identifiable information and is maintained by the team for determining eligibility and data collection purposes. The log also helps the study team to ensure that a participant who declined participation is not approached again upon admission to labor and delivery. IRB approval will be obtained prior to entering data in the screening and enrollment logs. The enrollment log will be a separate log that will contain the key linking participant information with the Participant ID. Each ID will be assigned to participants in a sequential order (e.g., 01-001, 01-002, 01-003….). Participant initials will not be included in the ID. Logs will be stored on password-protected desktops of the study team in a research folder accessible to the study team only. The participant IDs will be used on case report form (CRF) pages and the drain use questionnaire.

The team member will approach potentially eligible patients either in the office or clinic during the pre-operative visit. Patients who initially meet the enrollment criteria will be offered study

participation after a thorough presentation by the study PI, sub-investigator, or research coordinator at the pre-operative visit. At that time, all study risks will be discussed, and the consent form is signed should the patient choose to participate. Some participants may choose to take the consent materials home and return them later.

An updated list of consented participants will be available to the study team along with their participant numbers on a weekly basis. It is expected that at least twice as many participants will be consented as those that meet all inclusion/exclusion criteria at the time of the CD. Enrollment is considered "complete" when all inclusion and exclusion (contraindications) have been fully met

Drain Placement:

Described in Section 5

Drain Removal:

Described in Section 5

Data Collection:

User feedback is collected on a standardized form [see Appendix 1]. Limited participant data will be collected for the purposes of screening and device evaluation. [see Appendix 2] Sonographic images of drain placement may be recorded, printed, and placed in the participant's study file.

VISIT SCHEDULE

Visit	Visit 1	Visit 2	Visit 3
Procedures	Patient education and consent	Final Enrollment and Drain placement.	Post-partum visit
Timing	Pre-surgical	Drain Placement during CD/ Removal in Recovery Room	4-8 weeks post-partum
Evaluations	Screening using Medical History and current prenatal status	User evaluations Uterine tone assessments Ultrasounds Adverse events	Adverse events
Stipend	No	Yes	Yes

Participant Stipend:

Participants will be compensated at a rate of $100 upon completion of Visit 2 and an additional $50 for the completion of Visit 3 for a total of $150.

Duration of Participation:

Participants will be considered initially enrolled at the time of consent which may occur a week or more prior to the CD. Participants are expected to be followed for up to the post-partum visit.

ALTERNATIVES TO PARTICIPATION

Participants will receive the standard care per clinical indication regardless of participation in the study. Declining to participate will not affect clinical care.

WITHDRAWAL OF PARTICIPANTS

Participants will be withdrawn from the study if, after obtaining informed consent, the participant no longer meets the inclusion/exclusion criteria. If participants self-withdraw from the study, any data abstracted up until that point may be used in data analysis of participant characteristics. No further measurements or data will be collected after participant withdrawal or study completion.

ADVERSE EVENT REPORTING

An adverse event (AE) is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether considered related or not related to the study treatment. Adverse events will be collected during Visits 2 and 3.

A serious adverse event (SAE) is any untoward medical occurrence that:

- Results in death
- Is life-threatening
- Requires Participant hospitalization or prolongs the post-treatment hospitalization
- Results in persistent or significant disability or incapacity
- Causes a congenital anomaly in the offspring of the Participant, or
- Is considered an important medical event that jeopardizes the health of the Participant or requires surgical intervention to prevent one of the outcomes listed above

Any serious adverse events associated with use of the Investigational device will be submitted to the IRB in writing within 24 hours of learning about the SAE. Reportable new information will be reported to the IRB per the institutional policy.

7.0 RISK/BENEFIT

In accordance with the company's Risk Management Procedure, use-related risks were identified and evaluated prior to device design to develop design inputs and risk mitigation. Additional use-related risks were identified and evaluated, and risk reduction measures implemented for them during device development and testing. As a result, residual risk (post-risk-reduction) has been reduced to acceptable levels.

NON-SIGNNIFICANT RISK DETERMINATION

A significant-risk (SR) device study is defined by the United States Food and Drug Administration (https://www.fda.gov/media/75459/download) as one that:

- Is intended as an implant *and* presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject;
- or otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

A Non-Significant Risk (NSR) device study is one that does not meet the definition for an SR device study. This study poses no significant risks, does not meet the definition above, and tests a device that is considered exempt from FDA clearance. The only “off label” use of the drain is the addition of low-level suction. The Sponsor has identified the following risks and mitigations to further explain the justification for the NSR determination:

RISK & RISK MITIGATION

The following risks have been identified as “potential” based on similar devices:

- Perforation: The risk of perforation is mitigated by the placement of this drain under direct observation followed by an ultrasound confirming correct placement after closure. In addition, the drain is constructed of smooth, atraumatic materials.
- Endometritis: Endometritis is mitigated by selection of appropriate materials, selection of appropriate participants, and limited drain dwelling time. Endometritis can occur regardless of device use. To evaluate the occurrence of endometritis, participants will be followed out to the time of the post-partum visit.
- Vaginitis or tissue trauma: Vaginitis or tissue trauma is mitigated by using non-irritating materials and an atraumatic drain design. To evaluate for the occurrence of vaginitis or tissue trauma, participants will be followed out to the time of the post-partum visit.
- Infection: Infection is mitigated through the direction of drain placement, sterility of the drain, and limited time of exposure to the drain (~2.5 hours) in addition to careful participant selection.
- Loss of Participant Confidentiality: The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality. Every precaution will be taken to minimize this. The original signed consent documents will be stored in the research office which will be locked when not attended. Electronic logs will be stored in password protected desktop computers, accessible only to the research team. Data will

be stored according to institutional policy. At any given time, there will be 1 to 3 people from the Sponsor and/or site's research team present to abstract data. De-identified data will be collected in the database which will be accessible to outside institution team members. Data transferred out of the site will be de-identified data with the study ID number. The key containing the study ID number with the participant information will be accessible to the study team only and will be stored securely on password-protected computers. No genetic information will be collected for this study.

NOTE: Participation in the study is not expected to alter the likelihood of occurrence or severity of any standard surgical risks at the time of the CD. There is no risk to the fetus since the drain is placed after birth. Other than drain placement/removal and addition of suction during placement, there are no changes to the standard operative procedures. Participants are unlikely to experience sensation of the drain placement because it will be placed and removed while the participant is still under the influence of the epidural or spinal anesthesia. There is a small risk of unintentional loss of confidentiality. All efforts will be made to minimize this risk. There are no anticipated emotional, psychological, economic, legal, or social risks to the participants associated with this study.

For these reasons, it is the opinion of the Sponsor that this study design poses no significant risk to the participant.

POTENTIAL BENEFITS TO PARTICIPANTS

There is no proven direct benefit to participants in this study of the *DAISY* drain. Although similar devices have shown positive outcomes, benefits to participants in this study cannot be guaranteed.

8.0 DATA MANAGEMENT AND STATISTICAL ANALYSIS

The data collected will be marked with a study ID number to protect the confidentiality of each Participant. Only the research staff will have access to the link between the study ID and the patient's identifying information. The key will be stored in a password-protected document on a restricted access folder on the hospital network. Only the Principal Investigator, Sub-Investigator, and research team will have access to this document. This document will contain the participants' de-identified obstetric and medical history as relevant for the project.

Third-party data management and statistical analysis of de-identified data may be used. Analysis of the user responses will consist primarily of means, medians, and standard deviations. To accomplish this, the following points will be assigned to user responses.

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1 point	2 points	3 points	4 points	5 points

The Sponsor will follow up with any responses where the user has "disagreed" or "strongly disagreed" with the statement.

9.0 MONITORING

This study will engage multiple users who will be observed by the Sponsor's clinical engineering staff. Therefore, there will be minimal third-party monitoring of this small study.

10.0 REGULATORY REQUIREMENTS

This study is conducted under the requirements set forth by CFR 21 Part 812, 21CFR Part 50 (Informed Consent), and 21CFR Part 56 (IRB Review).

PERSONNEL RESPONSIBILITIES

Principal Investigator Responsibilities

a) Permit Sponsor/Monitor inspection of facilities and records

b) Permit inspection of facilities and records by government bodies

c) Submit protocol and informed consent to IRB and await approval

d) Submit proposed amendments to protocol and informed consent to IRB and await approval

e) Obtain informed consent of participants

f) Implement study in accordance with protocol

g) Complete CRFs/questionnaires and ensure all other users do the same

h) Explain deviations from protocol and report to monitor

i) Submit annual progress reports, final reports, and adverse effect reports to IRB and Sponsor

j) Record the receipt, disposition, and return of devices

k) Retain records for a minimum of two years following study completion (refer to IRB rules)

Sponsor Responsibilities

a) Assure IRB approval of protocol and informed consent is obtained

b) Select and train Monitors as needed

c) Select Sites and Investigators

d) Train Investigators in device use

e) Obtain curriculum vitae and proof of appropriate licensure of Investigators and study staff

f) Control shipment of devices

g) Investigate device-related adverse events

h) Maintain responsibility for data review and analysis

i) Obtain statement of financial disclosure for publication and presentation purposes

11.0 REFERENCES (In Alphabetical Order)

ACOG Practice Bulletin *Postpartum Hemorrhage*, Vol. 130, Number 4, October 2017.

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Evensen A., Anderson J.M., Fontaine P. Postpartum hemorrhage: prevention and treatment. *Am Fam Physician*. 2017;95(7):442-449.

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Kovacheva, V.P., Soens, M.A., Tsen, L.C. A Randomized, Double-blinded Trial of a "Rule of Threes" Algorithm *versus* Continuous Infusion of Oxytocin during Elective Cesarean Delivery. *Anesthesiology*. 2015;123(1) :92-100.

Rath, W. H., Postpartum hemorrhage-update on problems of definitions and diagnosis. *Acta*

12.0 STUDY ACKNOWLEDGEMENT AND CONFIDENTIALITY STATEMENT

The information in this document and future information which will be provided to you contains information that is confidential to Raydiant Oximetry, Inc. (hereinafter referred to as Raydiant) and may not be disclosed without prior written approval of Raydiant, unless such disclosure is required by federal or other laws or regulations. Information that is provided to you by Raydiant may be communicated by you to other persons who have a “need to know” the information to facilitate and implement the study in which you are participating. However, such persons must be informed that the information provided is confidential to Raydiant and may not be further disclosed by them.

The signatures of the investigator and the sponsor medical representative below constitute their approval of this protocol and agreement to the confidentiality statement above.

The investigator agrees to supervise all testing of the device and to ensure that requirements for obtaining informed consent are met.

The investigator and sponsor representative agree to:

- conduct the study according to the protocol and approved protocol amendments.
- conduct the study in accordance with the ethical principles stated in the latest version of the Declaration of Helsinki, the applicable guidelines for good clinical practices, and/or the applicable local regulations, whichever provide the greater protection of the individual.

Signature of Investigator Date

Investigator Name (Print)

Signature of Sponsor Representative / Title

APPENDIX 1

DEVICE USE QUESTIONNAIRE

Surgeon Name: _____

Obstetrician Fellow Resident (Circle one)

Years of experience in Obstetrical Surgery:_____

Date of Evaluation:_____ Placement #: 1 2 3 (Circle One)

Type of Suction Tube used (Brand & ID): _____

This Questionnaire aims to evaluate a set of aspects related to the use of the Daisy® device by the personnel in attendance. You are asked to indicate your level of agreement for each of the questions posed below, according to the scale of responses, place a check mark in the appropriate box.

	Strongly Agree	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
Device training clearly explained insertion, use and removal of the device.					
The Instructions for Use (IFU) are clear and concise.					
The Daisy was easy to insert through the cervix.					
The Daisy was easy to properly position within the uterus.					
The Daisy was easily visualized in the lower uterine segment at time of placement.					
The Tube of the Daisy was easily advanced through the vaginal canal.					
The Cap of the Daisy was easily identified & retrieved outside the introitus.					
The Cap of the Daisy was easy to remove from the Tube.					
The Cap of the Daisy had adequate retention in the Tube.					
The Daisy did not interfere with the closure of the hysterotomy incision.					
The Daisy Tube fits easily into standard suction tubing.					

The suction tubing was easy to secure to the leg of the participant using the provided adhesive Catheter Anchors.					
The Daisy remained in place until elective removal.					
The estimated blood loss from the uterus was easy to determine.					
Use of the Daisy did not interfere with routine OR or PACU practices.					
The force to remove the Daisy was acceptable.					
Overall, the Daisy was easy to use.					
The Daisy drained without intervention (clot removal). Describe any clots or interventions in the Comments below.					
Blood flow was easy to visualize through the Tube.					
Overall, the Daisy met all the user needs as intended.					

Other comments regarding the use of the Daisy: _____

_____

_____

_____

APPENDIX 2

PRIMARY PARTICIPANT DATA TO BE COLLECTED

Participant ID

Inclusion/Exclusion Criteria Met (yes/no)

Date of Consent

Date of Caesarean Section/Device Use

Reason for Caesarean Section

Period of Gestation

Pre-Operative Hemoglobin and Hematocrit

Post Operative Hemoglobin and Hematocrit

Cervical Dilation

Time of Device Insertion

Level of Suction

Uterine tone at three time points Post Partum

Time of Device Removal

Total Estimated Blood Loss (EBL)

Use of Uterotonics

Postpartum Uterine Ultrasound Scale (PUUS) at three time points Post Partum

Ultrasound evaluations of device position, uterine cavity size, fundal and lower uterine segment at three time points Post Partum

Adverse Events (Visits 2 and 3)