

Clinical Investigational Plan

PURSUIT:

A Registry to Further Develop the Understanding of the Real World use of the Eclipse™ System for Fecal Incontinence in Women

Protocol: CA007

Revision: A

01 Mar 19

Study Sponsor:

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PURSUIT Protocol Synopsis

Study Objective	A Registry to Further Develop the Understanding of the Real World use of the Eclipse™ System for Fecal Incontinence in Women
Study Design	A prospective, open label post-market registry to collect Patient Reported Outcomes and Fitting metrics (e.g. sizes used) in subjects using the Eclipse System in a commercial setting
Sites/ Subjects	Up to 150 subjects enrolled, in up to 25 sites
Study Population	All adult female patients with Fecal Incontinence who present at, or are identified at, participating sites are eligible. This includes patients who are newly prescribed Eclipse, and those already using Eclipse who return for an annual renewal visit during the enrollment period.
Study Duration	Per-patient registry participation will last one year from the date of Eclipse fitting. Sites will be allowed to enroll patients until the earlier of: 12/31/2019 or enrollment of 150 patients.
Outcomes Measures	<ol style="list-style-type: none">1. Fitting Metrics2. Change from baseline in mean scores on subject-reported outcomes related to symptoms as reported by St. Mark's (Vaizey) Incontinence Severity Score3. Eclipse Experience Feedback Assessment, including the Patient Global Impression of Improvement (PGI-I)
Eligibility Criteria	<ol style="list-style-type: none">1. Adult female2. Diagnosis of Fecal Incontinence3. Clinician recommendation of the Eclipse System4. Subject provides informed consent and HIPAA authorization

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1 Background

1.1 Feasibility Studies

Two feasibility studies were initially conducted to assess the fit and function of the Eclipse System in female subjects. These studies were approved by each site's Institutional Review Board (IRB) as non-significant risk (NSR) device investigations. In total, 86 subjects were fit with the Insert who wore it for up to 3 months. Initial safety and effectiveness outcomes were deemed acceptable for ongoing study.

1.2 LIFE Pivotal Study

The LIFE Study (Protocol CA003) was a multi-center, prospective, open label clinical trial conducted at 6 centers in the United States. As with the prior studies, all IRBs approved the trial as an NSR investigation. The objective of this pivotal trial was to evaluate the safety and effectiveness of the Eclipse System for the treatment of Fecal Incontinence (FI) in adult women.

Sixty-one (61) subjects met all study eligibility criteria and entered the 1-month Treatment Period to make up the Intent to Treat Cohort. The primary effectiveness endpoint was met: At 1 month, 78.7% of the ITT Cohort (95% CI, 66-88%, $p < 0.0001$) met the success criterion, defined as a 50% or more reduction in the number of FI episodes. Additionally, there were no serious device-related adverse events reported in the trial.

1.3 LIBERATE

The LIBERATE study was a multi-center, prospective, open label clinical trial conducted at 11 centers in the United States. As with the prior studies, all IRBs approved the trial as an NSR investigation. The objective of this study was to evaluate the safety and effectiveness among treatment responders between 3 and 12 months.

Seventy-three (73) subjects met all study eligibility criteria and entered the 12-month Treatment Period to make up the Intent to Treat Cohort. The primary effectiveness endpoint was met: At 3 months, 73% (95% CI 61-82%, $p < 0.0001$) of subjects met the success criterion, defined as a 50% or more reduction in the number of FI episodes. At 12 months, 70% (95% CI 58-80%, $p < 0.0001$) met the success criterion. Additionally, throughout the study there were no serious device-related adverse events reported.

1.4 LIBERATE PRO

The LIBERATE PRO registry study is an on-going, prospective, open label post-market registry to collect patient reported outcomes in subjects using the Eclipse System after completing the LIBERATE study. Patients who completed LIBERATE were offered new Eclipse devices to be used in the subsequent year, and were offered enrollment in LIBERATE PRO in which they would complete online surveys at 3, 6, 9, and 12 months. As the registry database was hosted and maintained by Pelvalon (sponsor) and no clinic visits were required of the patients, Pelvalon was the only site to seek and obtain IRB approval.

Eighteen (18) patients enrolled in the registry and completed one or more surveys. All but 2 patients have completed their participation and there have been no adverse events reported as part of LIBERATE PRO.

1.5 Description of the Eclipse System

1.5.1 Overview

The Eclipse System is a vaginal bowel control (VBC) therapy intended to provide bowel control for women with fecal incontinence. Manufactured by Pelvalon (Sunnyvale, CA), it is comprised of a non-surgical device placed in the vagina (referred to as the “Eclipse Insert”) and a pressure-regulated pump which is used to inflate and deflate the Insert.

1.5.2 The Sizing Kit

The Sizing Kit is a set of reusable fitting inserts (Sizers) which consist of the same stainless steel base and medical grade silicone coating as the Eclipse Insert, but without the balloon that is part of the Eclipse system. These reusable Sizers are available in the same base sizes as the Eclipse Insert, and can be reused after reprocessing in accordance with the Instructions for Use (IFU).

1.5.3 The Trial Insert

Prior to providing the Eclipse Insert to a subject, the clinician will use the Sizers and the Trial Insert to assess appropriate fit of the Eclipse Insert for each subject. The Trial Insert is composed of a base made of medical grade silicone, polycarbonate, and stainless steel, and a balloon made from medical grade silicone and polyurethane.

The Trial Insert consists of base-balloon configurations sized exactly as the Eclipse Inserts are sized and is intended for short-term use (1-2 weeks). This disposable Trial Insert allows the subject to try one or more Insert sizes (while keeping a fecal incontinence episode diary) during the Fitting Period before qualifying for and committing to the year-long use of the Eclipse Insert.

A silicone inflation tube connects to the balloon on one end, and to a self-closing luer valve (Valve) and cap on the other end which extends outside of the subject’s vagina. An optional extension tube can be added between the existing tube and the Valve to increase the length. The Valve allows the user to inflate or deflate the balloon with the Pump.

1.5.4 The Eclipse Insert

The Eclipse Insert is provided as a non-sterile unit for use by a single patient and is currently available in a range of base sizes with two (2) different balloon sizes. It is composed of a base made of medical grade silicone and stainless steel, and a balloon made of medical grade silicone and polyurethane. The Eclipse Insert is graphically depicted in **Figure 1**.

A silicone inflation tube connects to the balloon on one end, and to a self-closing valve (Valve) and cap on the other end which extends outside of the subject’s vagina. The Valve allows the user to inflate or deflate the balloon with the Pump. An optional extension tube can be added between the existing tube and the Valve to increase the length.

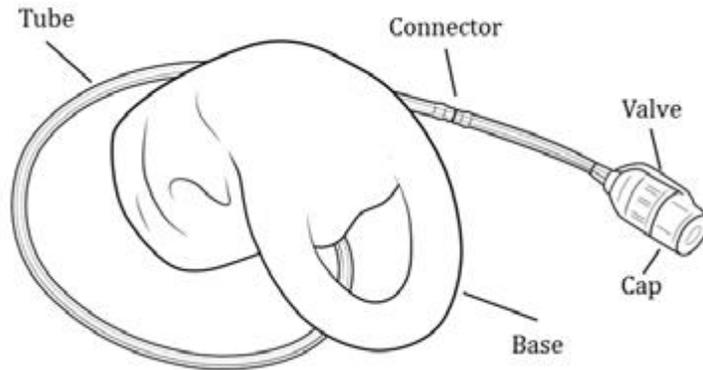


Figure 1. Eclipse Insert (inflated state)

1.5.5 The Pump

A pressure-regulated Pump (**Figure 2**) is provided to inflate and deflate the Insert. The Pump connects to the Insert via the Valve. The Pump has two ports that connect to the Valve: one end for adding air (labeled with a "+") and the other end for removing air (labeled with a "-"). Air is moved through the Pump by squeezing the pump body. During inflation, the Pump is squeezed seven to ten times. Seven pumping motions are required to adequately fill the balloon. The balloon will not over-inflate because any excess air is vented out by the regulator. When the balloon is fully inflated, the internal pressure is set to the venting pressure of the regulator.

Regulators are removable so that different balloon pressures can be achieved. Regulators and pumps are also designed for single-patient use only. Three different Regulators are available that regulate the balloon pressures to within the values listed in **Table 1**. The Pump is packaged with a Medium regulator attached. The Low and High Regulators may also be shipped separately.

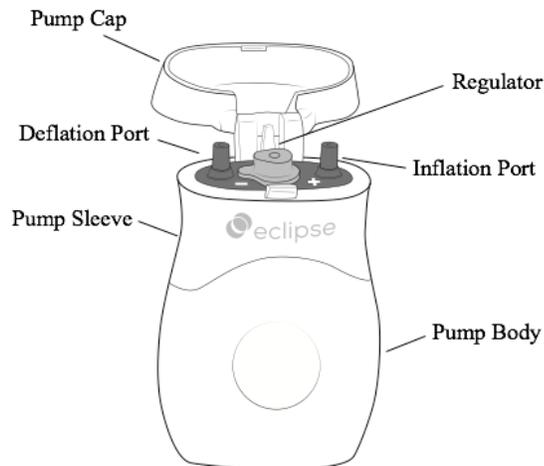


Figure 2. Pump

Table 1. Regulators and Associated Pressures

Regulator	Pressure at Full Inflation (mmHg)
Low	45-57
Medium	70-92
High	114-129

1.6 Mechanism of Action of the Eclipse System

The Insert is placed in a position similar to other vaginal devices, such as diaphragms, pessaries, and tampons, whose safety profiles are well-established.^{1,2,3} Insertion and removal, and inflation and deflation of the Insert, are under the control of the subject.

The Insert is designed to restore bowel continence in women with FI by replacing the normal continence function provided by the rectum and anal canal, which is complex and multi-factorial. The Insert utilizes the naturally overlapping potential spaces of the vagina and rectum to inhibit (or allow) stool passage in a user-controlled manner. Though separated by the conformable rectovaginal septum, much of the vagina and rectum effectively share the same space. When the rectum fills with stool, it expands, taking up more of this shared space. This is often palpable on a vaginal exam as the vagina conforms to the shape of the expanded rectum. Similarly, when an object is placed in the vagina, it is often palpable in the rectum. The redundant nature of the vaginal tissue makes it naturally conformable without discomfort or strain.

The Insert is designed such that when it is placed in the vagina and is in the deflated state, the rectal space is not occupied, allowing stool to pass through normally (see **Figure 3**, left). When the Insert is inflated, the vagina conforms around it, causing a reduction in rectal space, which helps the patient prevent unwanted stool passage (see **Figure 3**, right).

In **Figure 4** the Insert is shown in its deflated state. The base of the Insert is flexible to allow for ease of insertion and removal, as shown in **Figure 5**.

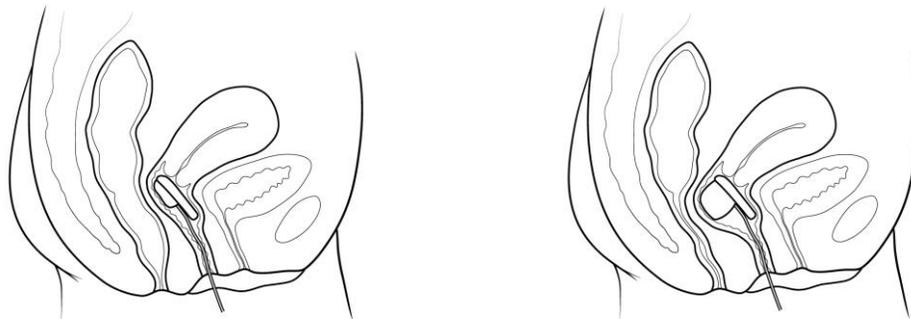


Figure 3. Insert; deflated (left), and inflated (right)

¹ Lone et al. A 5 year prospective study of vaginal pessary use for pelvic organ prolapse. *Int J Gynecol Obstet.* 114 (2011) 56-59.

² Clemons et al. Patient satisfaction and changes in prolapse and urinary symptoms in women who were fitted successfully with a pessary for pelvic organ prolapse. *Am J Obstet Gynecol* (2004) 190, 1025-9.

³ Bash, et al. Review of vaginal pessaries. *Obstetrical and Gynecological Survey* (2000) 55, 7, p455-460.

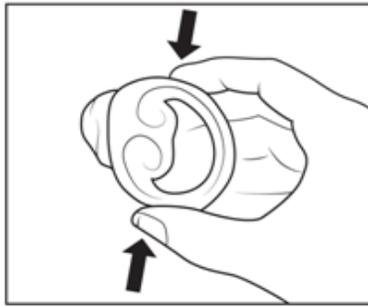


Figure 4. Deflated balloon

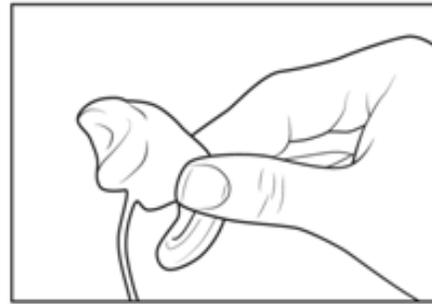


Figure 5. Folded Insert

1.7 Regulatory Status of the Eclipse System

The Eclipse System received marketing clearance from the U.S. Food and Drug Administration (FDA) on November 12, 2015.

1.8 Indications for Use

The Eclipse System is indicated for the treatment of fecal incontinence in adult women.

2 Current Study Description

2.1 Study Design

PURSUIT is a prospective, open label post-market registry to collect Fitting metrics (e.g. sizes used) and Patient Reported Outcomes in subjects using the Eclipse System in a commercial setting.

2.2 Target Population

Up to 150 subjects may be enrolled. All women being approached for inclusion into the PURSUIT registry must be adult female patients at participating sites and must have a diagnosis of Fecal Incontinence. She must be a new user of Eclipse or a patient returning to the clinic for her annual f/u visit. All participants will be required to provide informed consent and HIPAA authorization.

2.3 Recruitment and Enrollment

All patients who are deemed new suitable clinical candidates for the Eclipse System at a participating site will be invited to participate, as well as patients who are already using Eclipse, and return for an annual renewal visit during the enrollment period.

Potential subjects will be presented with information about how to sign up for the registry. . Each subject will be directed to a study-specific URL (searchable web page) where they can read an electronic Informed Consent Form and HIPAA Authorization Form. If they click on the "I agree to participate", "I consent", or similarly worded button they are taken to a registration form and are asked to provide their full name, date of birth, address, phone number and email address.

By navigating to and completing the registration page, this signifies the subject's willingness to participate in the online surveys and to receive future emails with the links to the online surveys to be completed, as well as to be contacted by the Sponsor by phone, email or in writing to remind

them to complete the surveys, and/or to provide clarifications about the information they have been provided in the completed surveys.

If a subject does not have access to, or is unwilling to provide, an email address, they can review a paper version of the Informed Consent Form and HIPAA Authorization form, and will be given an option to receive paper versions of all study surveys which can be filled out by hand and mailed back to the Sponsor. Similarly, if a site cannot easily access the URL, they can use the paper versions of all forms / surveys as well.

Enrollment in the post market registry, including the online data capture, will last for up to one year, and recruitment will end on 12/31/2019 or after 150 patients have been enrolled.

Sites will receive compensation for completing site surveys at each patient visit. Subjects will receive compensation for their time to complete each online (or returned hard copy) survey, which will be outlined in the Informed Consent form.

Enrollment will be completed once the annual visit is complete (approximately 1 year after enrollment begins).

2.4 Schedule of Events

At the Enrollment/Fitting visit, and subsequent in-office visits (as outlined below, in **Table 2**), patients and clinicians will access online surveys to complete the required data collection (or if necessary, use hard copies). Additionally, subjects will be sent an email with a link to the optional 3, 6, and 9 month surveys or mailed printed surveys, depending on chosen survey delivery method, to be completed at each of 3, 6, and 9 month time points as per the schedule in **Table 2**.

Table 2. Schedule of Events
(shaded columns indicate in-office visits)

	Enrollment / Fitting	Subsequent Fittings (if necessary)	Eclipse Visit	3 Mo	6 Mo	9 Mo	12 Mo
Informed Consent & HIPAA Authorization	X						
Bowel Health History	X						
Fitting Metrics	X	X	X				X
St. Marks (Vaizey) Assessment	X		X	X	X	X	X
Eclipse Experience Assessment (including PGI-I)		X	X	X	X	X	X

2.5 Surveys

The following questionnaires or surveys will be collected (as outlined in Table 2, above):

2.5.1 Bowel Health History

The Bowel Health History survey collects information regarding the patient's history with FI (symptoms and treatments), as well as other bowel health items, such as IBS and Rectal Prolapse. Also included are marketing questions about Eclipse and health insurance.

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2.5.2 Fitting Metrics

Clinicians will be asked at fitting visits, Eclipse visits, and annual renewals to provide information on the fitting process. For example, how many Inserts were used, and what sizes.

2.5.3 Eclipse Experience Assessment

Subjects will be asked, at in-office visits (fitting follow-ups and 12-month visits), to provide feedback on several Eclipse Experience questions related to perceptions of device comfort, satisfaction with usage and features, and impact on daily activities. This assessment includes the Patient Global Impression of Improvement (PGI-I), a validated global index that may be used to rate the response of a condition to a therapy on a scale from 1 (Very much better) to 7 (Very much worse). The PGI-I will be used to assess improvement of accidental bowel leakage in comparison to how it was prior to joining the registry or starting with Eclipse.

2.5.4 St. Marks (Vaizey) Incontinence Severity Score

The St. Mark's (Vaizey) Incontinence Severity Score is a measure of severity of FI symptoms, which has been shown to correlate with improvement in frequency of FI episodes and subjects' perceptions of relief.^{4,5,6} This score reflects the severity of FI and ranges from 0 (complete continence) to 24 (complete incontinence).

2.5.5 Optional 3, 6 and 9 Month Surveys

For the completion of online surveys at interim timepoints, a single survey generated using Survey Monkey containing the Eclipse Experience Assessment and the Vaizey score will be sent to subjects via a secure e-mail link or letter for completion approximately every 3 months after registering for the study. The electronic surveys are designed in such a way that there is no way to link a specific computer's IP address to the survey responses. For patients unable or unwilling to use the online survey, paper copies can be mailed to their addresses, with a pre-paid return envelope.

Subjects will have a 4 week window during which they can complete the surveys (every 3 months +/- 2 weeks) from their Eclipse Fitting date (or renewal date). If the surveys for the associated time period are not completed within this 4 week window, they will be counted as missed data points. Subjects will receive at least one, and no more than 5, reminders (by email and/or mail) to complete the surveys throughout the 4 week window.

3 Statistics

3.1 Analysis Population

The Analysis Data Set (ADS) will include all subjects who consent to participate in the PURSUIT registry and have at least an initial fitting, or, in the case of a patient already using Eclipse, be administered an annual renewal Eclipse.

⁴ Vaizey, CJ, et al Gut 1999;44:77-80 doi:10.1136/gut.44.1.77

⁵ Deutekom M, Terra MP, Dobben AC, Dijkgraaf MG, Felt-Bersma RJ, Stoker J, Bossuyt PM: Selecting an outcome measure for evaluating treatment in fecal incontinence. *Dis Colon Rectum* 2005, 48:2294-2301.

⁶ Maeda Y. Does the St. Mark's incontinence score reflect patients' perceptions? A review of 390 patients. *Dis Colon Rectum*. 2008 Apr;51(4):436-42

For any analyses that require a comparison to baseline data, or data collected at the initial fitting visit, patients who enroll at their Eclipse renewal will be omitted from the ADS, as they will not have baseline or fitting metrics.

3.2 Outcomes Measurements

Outcomes Measurements will be assessed at 12 months. Additional assessments may be made for interim (3, 6, 9-month) time points. Where applicable, changes from baseline will be evaluated. Baseline data will be defined as data provided at the initial Fitting Visit. If the patient was previously using the Eclipse System (e.g. joins the registry at a yearly follow-up/renewal), her baseline values will be omitted, and she will be excluded from analyses that require a baseline value.

The PGI-I, assessed as part of the Eclipse Experience Assessment, assesses changes from baseline in the control of bowel leakage, but does not have a baseline measurement. Instead, it is rated on a 7-point scale, where 1 is "Very much better" and 7 is "Very much worse". For a given time point, the average PGI-I score will be computed as the mean score across all completed assessments. Other Eclipse Experience Assessment questions will be summarized descriptively.

Fitting Metrics will be collected at the fitting visits, and summarized using descriptive statistics.

4 Other Study Details

4.1 Device Related Injuries and Product Complaints

All device-related adverse events that result in serious injury will be summarized and tabulated based on the Medical Device Reporting (MDR) database maintained by Pelvalon, as required per 21 CFR 803. Product complaints will be summarized and tabulated based on the product complaint records maintained by Pelvalon, as required per 21 CFR 820.198.

4.2 IRB Approval

Consistent with 21 CFR 56, and CFR 45 Part 160, and Subparts A and E of Part 164 (the Privacy Rule), this post market clinical study must be approved by an IRB prior to any subjects being enrolled.

4.3 Informed Consent

The Sponsor will use an electronic Informed Consent Form and HIPAA Authorization form which is consistent with regulatory requirements in 21 CFR 50 and 45 CFR 46, and will be approved by the governing IRB prior to use. If sites or patients are unable or unwilling to use the electronic forms, paper copies will be made available.

4.4 Monitoring

The study will not be monitored but data will be reviewed on an ongoing basis and sites and/or subjects may be contacted by phone, email, or in writing to provide clarification of discrepant or missing data.

4.5 Recordkeeping and Record Retention

Pelvalon will maintain evidence via an electronic / digital audit trail that electronic informed consent and HIPAA authorization was obtained prior to PHI being collected.

Pelvalon shall maintain study records for a minimum period of 2 years after the investigation is terminated or completed, or until the records are no longer required for purposes of supporting an FDA or International marketing approval, or such longer period as required by applicable law.

4.6 Reports

The site, with, or without Pelvalon's assistance shall prepare and submit the following complete, accurate, and timely reports:

- Progress reports. Pelvalon shall submit required progress reports to the reviewing IRB, as required by the IRB.
- Final report. Pelvalon shall submit a final report to the reviewing IRB within 6 months after termination or completion of the study.
- Other. A sponsor shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

4.7 Protection of Confidentiality

At all times throughout the clinical investigation, confidentiality will be observed by all parties involved. All data will be secured against unauthorized access, by limited access to the survey responses to the clinical research department personnel at Pelvalon. Privacy and confidentiality of information about each subject will be preserved in study reports and in any publication. Each subject participating in this study will be assigned a unique identifier. All surveys or extracts of data on the CRFs will be tracked, evaluated, and stored using this unique identifier.

The online surveys are generated using an online survey company called Survey Monkey, and are designed without the ability to link the respondent's IP address to the survey responses they submit. The responses are stored on Survey Monkey's servers which are located in the United States. Survey Monkey has a privacy policy in place to protect the confidentiality of both the Sponsor (creator of the surveys used in this research study) and the respondents. Survey Monkey's privacy policy can be found here: <https://www.surveymonkey.com/mp/policy/privacy-policy/>

Personal health information being collected in this registry dataset include the subject's name, date of birth, address, phone number and email address. The responses to the surveys will be downloaded at regular intervals and will be maintained for ease of access and reference in a separate excel, pdf or other electronic file extract on a Pelvalon shared cloud-based application called Box. Pelvalon has a signed Business Associates Agreement (BAA) with Box. Pelvalon's privacy policy can be found here: <http://eclipsesystem.com/privacy-policy/>

The data collected about each subject, and the results of this study, belong to Pelvalon and may be used for business purposes such as in publications, marketing materials, or regulatory submissions. An IRB-approved HIPAA authorization is required to be signed by each subject before their data can be collected and used for study purposes.

4.8 Trial Registration

This trial will be registered on clinicaltrials.gov website.

4.9 Data Collection and Data Management

Study data will be collected using surveys that are designed to be completed online. The survey questions will be built using an online survey tool called Survey Monkey. A secure link will be available to the clinician and patients for use during visits, and will be sent to each patient at the interim time points via email. In some cases, patients may be unable to complete the surveys electronically in which case they may be mailed to their home address with a pre-paid return

envelope for them to complete and return the survey in hard copy format. If hard copy surveys are collected these will be data entered by either Pelvalon Clinical or other delegated representatives of Pelvalon, and the hard copy surveys will be maintained as part of the audit trail.

4.10 Compensation to Patients

Patients will be compensated for data collection for any completed online surveys at any of the 3, 6, or 9-month time points. Additionally, patients may be compensated for their in-office visits, including the time it takes for them to complete the surveys in-office. The amounts to be provided to the patients will be stated in the Informed Consent.

4.11 Study Termination

The study may be discontinued at Pelvalon's discretion for the following reasons:

- Occurrence of unexpected adverse events or unanticipated adverse device effects
- New scientific information that shows that the study is no longer valid or necessary
- Insufficient recruitment of subjects
- Persistent subject non-compliance with survey completion
- Business reasons

If the study is discontinued or suspended prematurely, Pelvalon will notify all participating subjects and the IRB promptly.

4.12 Final Report

A final report will be completed, even if the study is prematurely terminated. The publication of the results will be at Pelvalon's discretion, with the exception of required results posting to clinicaltrials.gov.

5 Benefits and Risks

5.1 Benefits

The benefits of using the Eclipse System are that it is a self-managed, non-surgical device that may help a woman to control their accidental bowel leakage symptoms. It is possible that the Eclipse System may not provide any direct benefit to subjects in this research study. The information collected in this research study will help the company who manufactures the device to understand the longer term performance of the Eclipse System, which may benefit women who use this therapy in the future.

5.2 Risks

The main risk to being in this research study is a risk of sharing protected (personal) health information (PHI), and the potential breach of confidentiality.

5.3 Other Risks of the Device

The Eclipse System Patient Guide directs patients to report any of the following to their doctor if they occur:

- Foul odor or excessive vaginal discharge
- Difficulty urinating or defecating
- Significant bleeding not associated with menstruation
- New onset or worsening pelvic pain or discomfort

Good hygiene is important for the safe use of any vaginal insert. Proper care and cleaning of the Insert is important to avoid common side effects related to poor hygiene such as infection, bad odor, vaginal discharge and itching. Proper cleaning should reduce the likelihood of these events.

Some women may experience some changes in their bowel or urinary habits while wearing the Insert. They may also experience some mild discomfort during the insertion and/or removal of the Eclipse Insert in the same manner that inserting a tampon, diaphragm or pessary can be uncomfortable.

In previous clinical studies, over 200 women have worn the Insert with no serious device-related adverse events being reported. Non-serious adverse events that were reported include:

- Pelvic Cramping or Discomfort
- Pelvic Pain
- Vaginal Erythema (redness) / Petechiae (a small red or purple spot caused by bleeding)
- Vaginal Discharge
- Vaginal Abrasion
- Vaginal Bleeding
- Vaginal Spotting
- Vaginal Ecchymosis (bruising)
- Vaginal Irritation
- Yeast Infection (Candidiasis)
- Lower Urinary Tract Infection
- Urinary Incontinence
- Urinary Urgency / Frequency
- Difficulty with Urinary Voiding
- Difficulty with Stool Evacuation

The use of the study device in pregnant women has not been evaluated and may involve risks to you (or to an embryo or fetus, if you are, or may become pregnant).

The safety and effectiveness of the Eclipse System have not been evaluated in women who use an IUD.

There may also be risks to using the Eclipse Insert that are not known at this time.

Warnings

The Insert contains metal, so it must be removed before obtaining an MRI. An MRI may cause heating or movement of the Insert, which could lead to adverse events.

Before obtaining a pelvic X-ray, women should consult with their physician about whether or not to remove the Insert as the Insert may obscure images.

The Insert and the Pump are for single-patient use only, so should not be shared with anyone. Sharing the Insert and/or Pump could result in transmission of disease and/or infection.

6 Revision Record

Document	Revision	Section amendment and rationale
Protocol	A	Initial draft

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