

Eclipse™ System Instructions for Use

Eclipse System Components

The Eclipse System includes two main components, an Insert (**Figure 1**) and a Pump (**Figure 2**). The Insert is used intravaginally, is insertable/removable by the patient, and includes a Balloon that when inflated, exerts a force posteriorly (trans-vaginally) against the wall in the rectum resulting in a decrease in the lumen of the rectum (**Figures 4 and 5**). The compression of the rectal space results in decreased frequency of fecal incontinence events. The Eclipse System also contains two tools for the fitting process: a Sizing Kit, consisting of Sizers in each available Insert Base size, and a Trial Insert. Each component is described below.

- **Sizing Kit / Sizers:**

Reusable (multi-patient) Insert Bases (Sizers), intended to aid in selecting appropriate Trial Insert Sizes. Sizers are only used in a clinical setting (<60 minutes) and are not intended to be taken home. (**Figure 3**)

- **Trial Insert (Insert*):**

Single-patient-use vaginal insert intended for short term use (approximately 1 week, but no more than 2 weeks) during the fitting and evaluation process. Multiple Trial Inserts may be attempted to achieve a correct fit. The Trial Inserts are identifiable by their white color. (**Figure 1**)

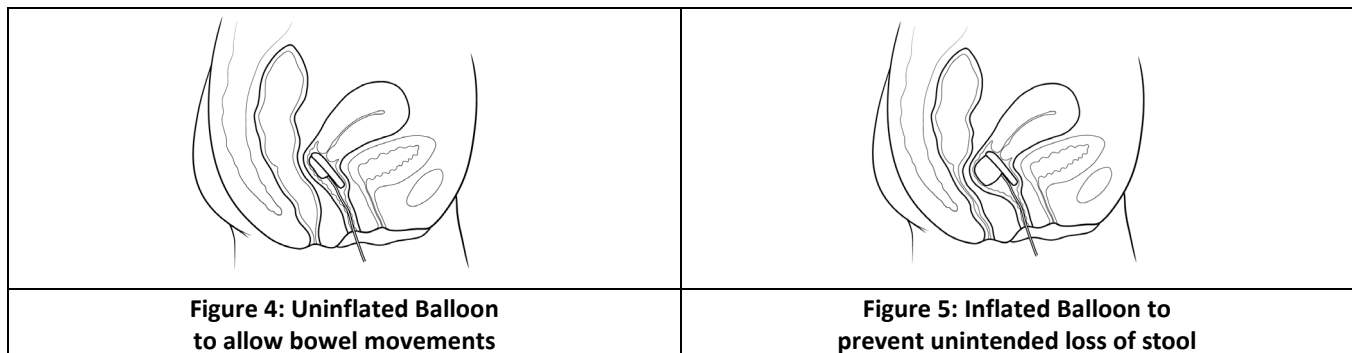
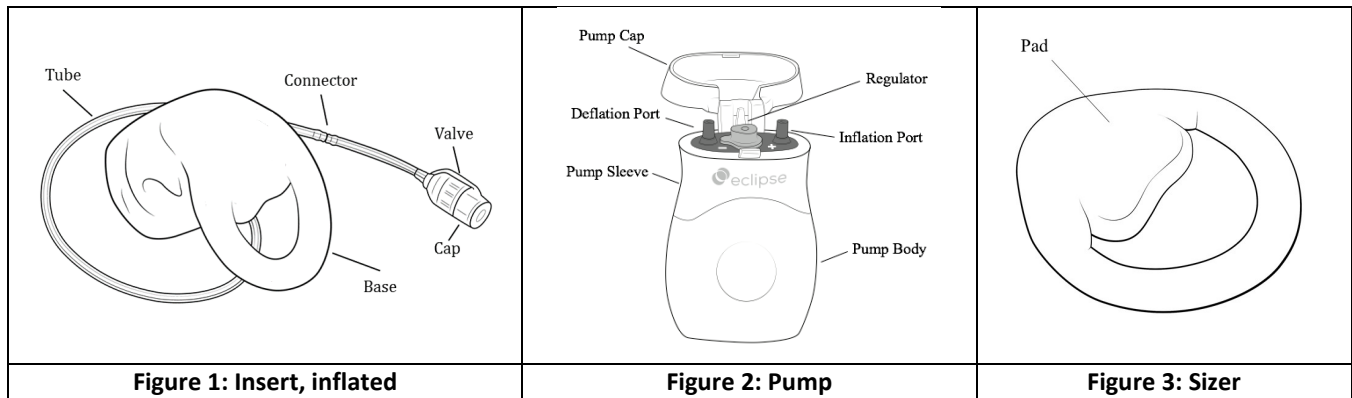
- **Eclipse Insert (Insert*):**

Single-patient-use vaginal insert intended for longer-term use (up to 1 year). The Eclipse Inserts are identifiable by their indigo color. (**Figure 1**)

- **Pump:**

The Pump is used by the patient for inflating and deflating the Balloon with a goal of improving control over bowel movements. The Pump includes a replaceable Regulator which regulates the maximum pressure of the Insert's Balloon. Regulators are available for different pressure levels, and can be replaced to adjust the maximum pressure of the Insert's Balloon. (**Figure 2**)

**Throughout the following sections, the term "Insert" applies to both the Trial Insert and the Eclipse Insert. Other than the duration of use, the usage instructions are the same for both Inserts.*





Indications for Use

The Eclipse System is indicated for the treatment of fecal incontinence in adult women. It is intended for prescription use.

Contraindications

- Presence of vaginal infection
- Presence of open vaginal wound

Warnings

- This product contains metal and so must be removed before undergoing an MRI, in order to prevent any potential adverse events that may occur due to heating or movement of the Insert during the MRI.
- Before obtaining a pelvic X-ray, patients should consult their physician about whether or not to remove the Eclipse Insert as the Insert may obscure images.
- The Eclipse Insert and the Pump are for single-patient use only.
- To prevent infection, do not reuse a Sizer that has not been reprocessed per the instructions in the IFU.
- In the case of a foul odor or excessive vaginal discharge, difficulty urinating or defecating, significant bleeding not associated with menstruation, or any new onset or worsening pelvic pain or discomfort, the Insert should be immediately removed and the patient should immediately notify their physician.

Precautions

- This device should only be prescribed by physicians with expertise in the evaluation of pelvic floor anatomy.
- The Trial Insert should not be used for longer than 2 weeks, as it is not designed for long-term use. The Eclipse Insert should be used for long-term use.
- Prior to initial use, ensure that this entire Instructions for Use document is read and understood.
- Prior to each use, inspect the Sizer, Insert, and/or Pump for possible damage. If damaged, do not use.
- To remove the Insert from the vagina, do not pull the Tube. Pulling on the Tube may damage the Insert, Connector, or Tube.
- To disconnect the Pump from the Insert Valve, grasp the Valve, do not pull on the Tube. Pulling on the Tube may damage the Insert, Connector, or Tube.
- Patients should continue the use of any treatment they are using for vaginal atrophy (e.g., topical estrogen cream).
- Care should be taken to avoid use in patients with severe vaginal atrophy that would prevent safe, effective, or comfortable use of the Insert.
- The safety and effectiveness of the Eclipse System have not been evaluated in patients with pelvic organ prolapse beyond the plane of the hymen or who are pregnant.
- The safety and effectiveness of the Eclipse System have not been evaluated in women who use an IUD.
- Use of the Eclipse System after a recent hysterectomy may compromise the integrity of the vaginal cuff repair.
- The safety and effectiveness of the Eclipse System for use in women with less than 4 episodes of fecal incontinence over a 2-week period have not been demonstrated.

Directions for Use

Preparing the Device:

- The Insert and the Pump are supplied non-sterile, for single-patient use.
- Inflate and deflate the Balloon and inspect the device for possible damage. Instructions for deflation and inflation are provided below, under "Balloon Inflation and Deflation".

Balloon Inflation and Deflation:

- Be sure not to get any lubricant on either the Inflation or Deflation Ports on the Pump or the entrance to the Valve. This can prevent the Valve from remaining connected to the Pump.
 - Change gloves as often as necessary to prevent lubricant transfer.
 - If the Valve unintentionally disconnects from the Pump, clean both with IPA.

- Open the Valve Cap at the end of the Tube (**Figure 6**).

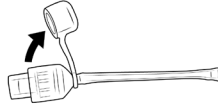


Figure 6: Open Valve Cap

- To inflate, connect the Pump's Inflation Port (designated by a "+" sign) to the Valve. Push the Pump and Valve together to engage. It is not necessary to twist. (**Figure 7**)
- Squeeze the Pump multiple times until excess air is vented out of the Regulator (7 – 10 pumps). There is no harm in pumping more than necessary to fill the Balloon, since any excess air is vented out of the Regulator. This ensures that the internal pressure of the Balloon is set to the value of the Regulator. The Pump should be squeezed smoothly and evenly; avoid short, fast squeezes as they may move less air into the Balloon.
- Separate the Pump and the Valve by pulling them apart. Do not pull on the Insert's Tube to separate the Pump and Valve as it may cause damage to the Insert, Connector, or Tube. Instead, grasp the Valve and the Pump, as shown in **Figure 8**.

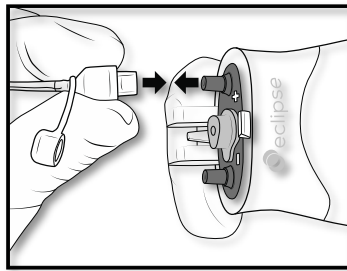


Figure 7: Attach the Inflation side of the Pump to the Valve

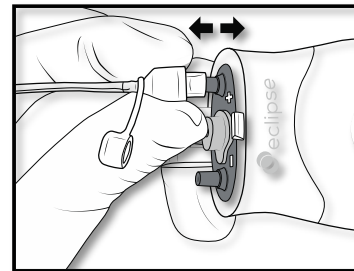


Figure 8: Disconnect the Valve from the Pump

- To deflate, connect the Pump's Deflation Port (designated by a "-" sign) to the Valve. Push the Pump and Valve together to engage. It is not necessary to twist. (**Figure 9**)
- Squeeze the Pump multiple times until the Pump Body stays compressed, indicating all the air has been removed from the Insert.
- Separate the Pump and the Valve by pulling them apart. Do not pull on the Tube to separate the Pump and Valve as it may cause damage to the Insert, Connector, or Tube (**Figure 10**).

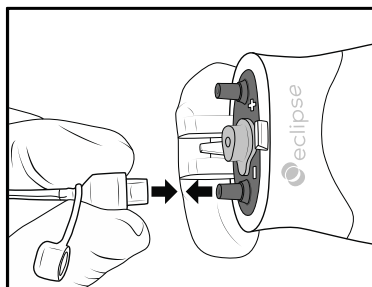


Figure 9: Attach the Deflation side of the Pump to the Valve

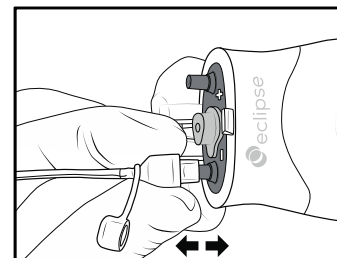


Figure 10: Disconnect the Valve from the Pump



Initial Fitting and Placement of the Insert: (note – removal instructions provided below under “Device Removal”)

A. Evaluate Anatomy

- Evaluate the patient's vaginal tissue for atrophy. Continue any existing prescription of vaginal estrogen cream, and consider the prescription of vaginal estrogen cream for patients with mild or moderate atrophy. Please refer to the Prescribing Information of the relevant vaginal estrogen cream and discuss and consider all risks with the patient.
- Remove any tampon or other device the patient has inserted in her vagina. Perform a standard pelvic exam and estimate an appropriate Insert size by:
 - Estimating the maximum vaginal width using index and middle fingers.
 - Estimating the vaginal length (from vaginal apex [cervix or cuff] to inferior pubic ramus).

B. Estimate Insert Size Using Sizing Kit

- Lubrication can be applied to the vaginal opening for patient comfort.
- Select the appropriate Sizer from the Sizing Kit to test your estimate of the appropriate Insert size.
- Before using the Sizer, inspect to make sure the Sizers are free of any damage (e.g. cracks, tears or holes) and verify that the Sizer flexes and recovers. Dispose of Sizers that do not meet these inspection criteria.
- Place the Sizer in the vagina by folding and guiding it past the introitus, pad-end first. For patient comfort, keep the Sizer folded until it is as far inside the vagina as you can reach. After releasing the Sizer, allow it to settle into position. If it can be manually adjusted slightly deeper once un-folded, do so. Once inserted, the patient can perform a Kegel maneuver to help the device settle into the appropriate position.
- Use a finger to check the fit of the Sizer; it is well-fit when there is approximately one finger-breadth (~1cm) of clearance between the Sizer and the vaginal walls.
- To estimate the appropriate Balloon size, use a finger to assess the amount of space below the Sizer by deflecting the posterior wall of the vagina.
- Have the patient perform a Valsalva maneuver to make sure the Sizer remains stable and is not expelled.
- The patient's comfort in a seated and standing position can also be assessed at this point.
- Multiple sizes of Sizers may be tried to determine the appropriate Base size. Available options are provided below in the Insert Sizes and Measurements table (**Table 4**) at the end of the instructions.
- Ensure that each Sizer is removed from the patient and accounted for before fitting a Trial Insert or another Sizer in the same patient.

C. Balloon Sizing

- For initial fitting, use a Trial Insert to evaluate the selected size. The Trial Insert is intended for use during the fitting process and at home, temporarily, over a period of approximately 1 week but no more than 2 weeks. This allows a patient to ensure fit, comfort, and patient satisfaction.
 - Caution: Trial Insert should not be worn for longer than 2 weeks.
- Ensure the Balloon on the Insert is fully deflated (**Figure 11**). Instructions for deflation and inflation are provided above, under “Balloon Inflation and Deflation”.
- Fold the Insert along its length (**Figure 12**) and insert it into the vagina, Balloon-end first, with the Balloon facing posteriorly. (**Figure 13**)

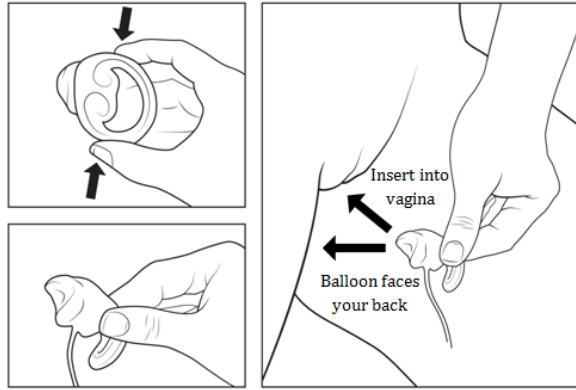


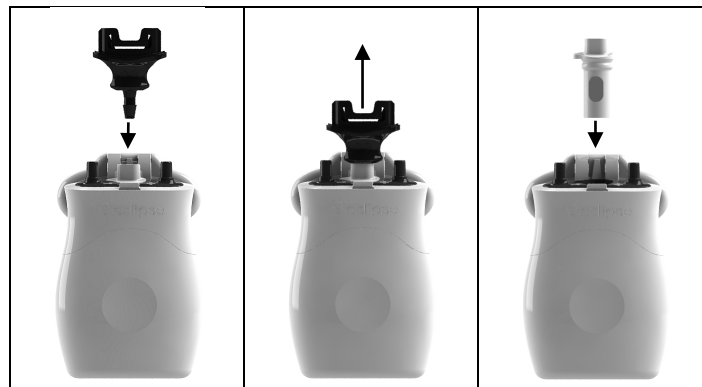
Figure 11: Deflated Balloon
Figure 12: Folded Insert

**Figure 13: Folded Insert,
 Positioned for Insertion**

- The Insert should naturally come to rest in the proximal vagina adjacent to the rectum, in a similar area to a diaphragm, pessary, or tampon. If it can be manually moved proximally once un-folded, do so. Once inserted, the patient can perform a Kegel maneuver to help the device settle into the appropriate position.
- Prior to inflating the Balloon, you may perform a manual vaginal exam to assess device fit, as done with the Sizer. About a finger's breadth of clearance should be minimally available between the device and the vaginal walls.
- Inflate the Balloon slowly until it is fully inflated (when air vents from the Regulator; 7-10 pumps). Inflating the Balloon may cause a change in Insert positioning. Perform the following steps in Section D to assure an appropriate fit.
 - Note: see additional instructions below for fitting the Insert in women with a prior hysterectomy.

D. Fit Assessment Procedure:

- Check for patient comfort.
- Check to ensure that there is still about a finger's breadth of clearance between the device and the vaginal walls.
- A properly fit Insert should feel secure but not tight, should sit fully behind the pubic ramus, and the Balloon should be proximal to perineal body (i.e. deeper in the vagina).
- If the Insert is uncomfortable, unstable or appears to be improperly fit with the Balloon inflated, a different Balloon size or a different Balloon/Base configuration can be tried to achieve a better fit.
- If only a small adjustment to Balloon size or pressure is required, more or less air can be added by changing the Regulator on the Pump. Regulators are removable so that different Balloon pressures can be achieved. Regulators are single-patient use only. The Pump comes installed with a medium Regulator. The other sizes of Regulators are shipped separately. If the patient is uncomfortable with the medium Regulator, try a Regulator with a lower pressure (**Figure 14**). If there is room for additional inflation, try a Regulator with a greater pressure. Note that the lower pressure Regulators should only be used temporarily as the patient adjusts to the Insert (e.g. approximately 1 week); a medium or higher level Regulator should be used for treatment.



**Figure 14: Exchanging the Regulator with the Removal Tool
 (Regulator removal can also be performed manually)**

- The following Regulators are available:

Table 1: Regulator Pressures	
Regulator #	Pressure at Full Inflation (mmHg)
Low	45-57
MedLo	58-69
Medium*	70-92
MedHi	93-113
High	114-129

*A Medium Regulator is pre-loaded on the Pump.

- With the Balloon inflated, perform a rectal exam to evaluate reduction in rectal space created by the device.
- Try a different Balloon size or a different Base/Balloon configuration, or adjust the amount of air in the Balloon (by changing the Regulator) as necessary to optimize the reduction in rectal space, the device fit in the vagina, and overall patient comfort.
 - If the Balloon protrusion is easily moved with digital pressure, a device with a larger base may be selected.
 - If the protrusion is stable, but could be more occlusive, consider a larger Balloon.
- With the device in place and inflated, have the patient perform a mild Valsalva maneuver to make sure the device remains stable and is not pushed out.
 - If the device falls below the symphysis into the mid-vaginal plane, and does not retract after the Valsalva, consider a different size device.
 - It may be helpful to perform the Valsalva in high lithotomy position (simulated squat).
- Have the patient sit up, stand, and walk about the exam room to ensure comfort in different positions.
- Confirm the patient's ability to void her bladder. There should not be any interference with normal urinary voiding.
- The final part of the fitting assessment is an at-home trial period. Instruct the patient to wear the Trial Insert for approximately one week to confirm fit, comfort and patient satisfaction. If it is immediately apparent that the Insert does not fit correctly, the patient should discontinue use. The fitting assessment can be repeated with different sizes of Trial Insert as needed.
 - Caution: Trial Insert should not be worn for longer than 2 weeks.

Notes on Fitting Insert for Women with a Prior Hysterectomy

- The insertion steps are not different in a woman with a prior hysterectomy. However, women with prior hysterectomy may in some cases have a shorter vaginal length, which may increase the difficulty of achieving a successful fit.
- Smaller Base sizes may be more appropriate for women with hysterectomies.
- Once fit, the treatment effect is the same in women with and without hysterectomies.
- There is no difference in use or care of the Insert.
- See **Figure 15** for an example of an Insert fit in a hysterectomized woman.

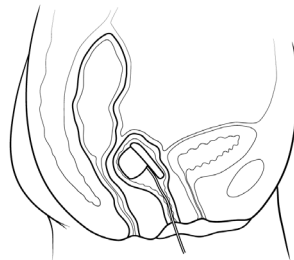


Figure 15: Insert in post-hysterectomy anatomy



Device Removal:

- For removal of the Insert, the Balloon should be deflated. The Base of the Insert can then be grasped by a finger and eased out of the vagina.
 - Note: To remove Insert from the vagina, do not pull the Tube. Pulling on the Tube may damage the Insert, Connector, or Tube. Grasp the Insert directly.
- Discard each Trial Insert used in the fitting process, unless it is the one sent home with the patient.

Adjusting Tube Length:

- Patients may desire to shorten or lengthen their Tube depending on how they prefer to wear it, by either cutting the Tube or adding an Extension to the Tube.
- If the patient desires a shorter Tube or a shorter Extension, detach the Connector from the Insert's Tube. Using a clean blade or scissors, cut the Tube to the desired length, making the cut as flush as possible. To reattach, press the Connector into the respective Tube until the Tube is touching the middle portion of the Connector, well past the barb.
- If the patient desires a longer Tube, an Extension can be added. Each Extension consists of a 12" length of Tube with a Connector. It can be trimmed if less than 12" of extension is required.
 - To add the Extension to the patient's Insert:
 - Detach the Connector from the portion of the Tube that is connected to the Balloon, leaving the Connector attached to the short portion of the Tube that is attached to the Valve.
 - Attach the portion of the Tube that is connected to the Balloon to the Connector on the Extension.
 - Attach the other end of the Extension to the Connector that is attached to the portion of tubing that is connected to the Valve.
 - Connectors are attached to the Tube by pressing them into the Tube until the Tube is touching the middle portion of the Connector, well past the barb.
 - Note: When adjusting the length of an Insert with an Extension, it is preferable to shorten the Extension, not the Tube on the Insert.

Patient Education:

- Demonstrate device inflation and deflation to the patient using the Pump.
- Allow the patient to independently place the Insert in her vagina. With the Insert inserted and the Balloon inflated by the patient, perform a manual exam of the Insert in the vagina to ensure it is in the appropriate position and inflated correctly.
- The patient should be thoroughly instructed in the proper techniques for removal and insertion. Demonstrate appropriate technique for Insert insertion and removal, including correct Insert orientation, and allow patient to practice insertion and removal.

Give the patient a copy of the **Eclipse System Patient Guide** (booklet) to take home and instruct the patient on proper daily use of the Eclipse System, as follows:

- The Balloon should remain inflated to protect the patient against unwanted loss of stool.
- The Balloon should be deflated for intentional bowel movements.
- Air should be added (as described above under "Balloon Inflation and Deflation") to the Balloon at least three times per day (minimally including morning, night and after bowel movements), as some air will leak out over time.
- Patients should be instructed to self-remove and clean the Insert on a weekly basis, to remove and clean daily if worn during menstruation, and to remove prior to sexual intercourse. Patients should also be instructed to disinfect the Insert if it becomes soiled.
- Refer the patient to the **Eclipse System Patient Guide** for cleaning and disinfection instructions.
- Patients should be instructed to wear the Trial Insert for approximately 1 week (but no longer than 2 weeks), but to discontinue use if they feel the fit is not right. Additional sizes of Trial Insert may be attempted.
 - Caution: Trial Insert is not designed for long-term use. Only the Eclipse Insert is designed for use up to 1 year.
- Patients should be informed that the Eclipse Insert should be replaced yearly.



Follow-up Fitting Assessment:

- After the initial fitting visit, patients should return within approximately one week to confirm the initial fitting, making sure the Trial Insert stayed in place and remained comfortable. The Trial Insert should not be worn for longer than two weeks, but if the first Trial Insert is not a correct fit, additional sizes may be attempted in repeated 1-week trial periods.
 - Caution: Trial Insert is not designed for long-term use.
- At this follow-up, check the fit parameters as described above (under Fit Assessment Procedure), and if necessary, try a new size.
- A vaginal exam should also be performed to check for any signs of an adverse event.
- If the fit is found to be satisfactory at the initial follow-up visit, then the patient should receive an Eclipse Insert for treatment.
- Patients should return for routine follow-ups at physician's discretion, to fit the needs of the patient. At these visits, the fitting parameters should be re-checked, and the vagina should be re-inspected for any signs of an adverse event.
- The Eclipse Insert and the Pump should be replaced yearly.

Reprocessing Sizers:

- Sizers must be cleaned and high-level disinfected (or cleaned and steam-sterilized) after use, so that they can be used for subsequent patients.
- Note: An effective cleaning process is essential to ensure effective high level disinfection or steam sterilization. Do not allow soil to dry on the Sizer prior to cleaning.
- Clean the Sizer as soon as possible after use. If it is not possible to clean/rinse the Sizer immediately following use, place the Sizer in a basin with clean lukewarm tap water until proper cleaning can be commenced per the instructions below.
- Use the following instructions:
 - 1. Cleaning (Prior to High Level Disinfection/Sterilization)**
 - a. Get a bowl ready for cleaning. Fill it with a gallon of lukewarm water, enough to submerge the Sizer(s), and add 1 teaspoon of mild dishwashing liquid detergent for every gallon of water.
 - b. Have several lint-free wipes, such as gauze pads, ready.
 - c. Rinse under running lukewarm tap water for at least 1 minute.
 - d. Submerge in the soapy water for at least 2 minutes.
 - e. Scrub the Sizer(s) for at least 1 minute using a lint-free wipe. Pay extra attention to the corners inside the Base ring. Use extra wipes as needed.
 - f. Rinse the Sizer(s) under running lukewarm tap water for at least 1 minute.
 - g. Dry the Sizer(s) thoroughly with a fresh wipe.
 - h. Check the Insert for damage or any remaining unclean areas before use. If any visible soil remains, repeat the cleaning process and re-check the device. After several cleanings, if visible soil cannot be removed, dispose of the device.
 - 2. High Level Disinfection or Sterilization (Either Method Can Be Used)**
 - a. The high-level disinfection method for the Sizer is as follows:
 - i. Prepare a ready-to-use OPA (Ortho-phthalaldehyde) Solution with a concentration of at least 0.55% using the manufacturer's instructions.
 - ii. Fully immerse the device(s) in the disinfection solution for 12 minutes at a minimum of 20°C.
 - iii. Fully immerse the device(s) for rinsing in a minimum of 2 gallons (7.6 Liters) of room temperature, potable water for a minimum of 1 minute. Repeat rinsing 2 more times for a total of 3 rinses using fresh potable water for each rinse.
 - iv. Thoroughly dry the device with a clean, lint-free wipe or towel.
 - v. Storage following high-level disinfection: Sizers should be stored in a clean, sealed plastic bag or cleaned plastic bin with lid after high-level disinfection until their next use.



- b. The sterilization method for the Sizer is as follows:
 - i. Use steam-sterilization (autoclave).
 - ii. Prepare the device(s) for sterilization by placing in an autoclave sterilization pouch.
 - iii. Use a 132°C prevacuum air removal cycle with an exposure time of 4 minutes; followed by a dry time of 20 minutes.
 - iv. Storage following sterilization: Sizers should be stored in their autoclave pouch after steam sterilization until their next use.

Storage Conditions

- Inserts: Store in a dry, room temperature environment.
- Sizers: See storage instructions included in high-level disinfection and steam sterilization section.

Risks Associated with Use of the Eclipse System

In a clinical trial to study the Eclipse System, 117 women participated in the Insert fitting process, and 61 women entered a 1-month Treatment Period evaluation. Among those women, the following events were observed. All of these events were mild or moderate, and no surgical intervention was required to address any of these events. The majority (72%) of events occurred during the Fitting Period.

Table 2: Risks Observed During the Fitting Period

Type of Risk	# Subjects	Percent
<i>Serious risks</i>		
None	0 / 117	0%
<i>Non-serious risks</i>		
Pelvic Cramping or Discomfort	17 / 117	15%
Pelvic Pain	9 / 117	8%
Urinary Incontinence	8 / 117	7%
Vaginal Spotting	8 / 117	7%
Urinary Urgency / Frequency	6 / 117	5%
Vaginal Erythema / Petechiae	5 / 117	4%
Vaginal Discharge	3 / 117	3%
Vaginal Abrasion	3 / 117	3%
Vaginal Bleeding	2 / 117	2%
Difficulty with Stool Evacuation	2 / 117	2%
Difficulty with Urinary Voiding	1 / 117	1%
Vaginal Ecchymosis or Bruising	1 / 117	1%
Vaginal Irritation	1 / 117	1%
Total subjects*	49 / 117	42%

* Total subjects is not the sum of above numbers, as subjects may have experienced multiple events during the same time period.



Table 3: Risks Observed During the 1-Month Treatment Period

Type of Risk	# Subjects	Percent
<i>Serious risk</i>		
None	0 / 61	0%
<i>Non-serious risk</i>		
Pelvic Cramping or Discomfort	6 / 61	10%
Vaginal Bleeding	2 / 61	3%
Pelvic Pain	2 / 61	3%
Vaginal Abrasion	2 / 61	3%
Urinary Incontinence	1 / 61	2%
Difficulty with Urinary Voiding	1 / 61	2%
Vaginal Discharge	1 / 61	2%
Vaginal Erythema / Petechiae	1 / 61	2%
Yeast Infection (Candidiasis)	1 / 61	2%
Difficulty with Stool Evacuation	1 / 61	2%
Total subjects*	14 / 61	23%

* Total subjects is not the sum of above numbers, as subjects may have experienced multiple events during the same time period.

There is a risk of device malfunction in which the patient is not able to deflate the Balloon. Instruct patients to follow these troubleshooting instructions:

- Ensure they are using the correct side of the Pump: the deflation side, indicated by the “-” sign.
- If they can remove the Insert without deflating it, do so, and attempt to deflate it.
- They may be able to deflate the Insert by disconnecting the Tube from the Connector and allowing air to escape from the Tube.
- If they are unable to remove the Insert, and cannot deflate it, they should call their healthcare provider.
- In the event of significant pain or discomfort, if they are unable to deflate the Insert, and cannot disconnect the Tube from the Connector, they should cut the Inflation Tube (as close to the Connector as possible) to deflate the Balloon.

Clinical Summary

The Eclipse System has been the subject of 3 clinical studies: two feasibility studies and a pivotal study. Across all studies, 219 subjects have worn the device.

Feasibility Studies

The goal of these studies was to evaluate the proof of concept of the Eclipse System by evaluating the device’s stability and positioning, rectal occlusion, and patient comfort. The fitting process, comfort, and safety were evaluated, as well as usability feedback from those subjects suffering from FI.

In the 102 subjects exposed to the device, there were no serious device-related adverse events and 9 non-serious, device-related adverse events. All 9 were mild (minor bleeding/superficial cuts due to tissue stretching upon insertion/removal [3] or minor ecchymosis [6]) and resolved quickly without medical intervention other than vaginal estrogen cream.

Pivotal Study

Study Design

The study design was a multi-center, prospective, open-label, safety and effectiveness study of the Eclipse System in women with fecal incontinence. To be eligible for treatment, patients must have met several screening criteria, including a 6-month history of FI, ≥ (greater than or equal to) 4 FI episodes (defined as major or minor soiling) during their 2-week baseline diary, and successful fitting of the Insert. The primary endpoint was reduction of FI episodes (as recorded in a



patient diary) after 1 month of treatment with the Eclipse System (Treatment Period) compared to baseline without the device. A study success criteria was $\geq 40\%$ of subjects reporting $\geq 50\%$ reduction in FI episodes during the on-device period as compared to the baseline period. Subjects were invited to enter an Optional Treatment Period for an additional two months, for a total of 3 months of treatment.

Study Results

Two hundred (200) subjects were consented with 61 subjects (31%) entering the Treatment Period. The most common reason for screening exclusions prior to fitting was insufficient frequency of FI episodes during the baseline period (< 4 FI episodes in two weeks), which accounted for 49% of exclusions prior to fitting. Of the 110 patients who continued to the fitting assessment, 49 (45%) did not achieve a successful fit or successfully complete the fitting assessment.

Safety

There were no serious device-related adverse events reported. All device-related adverse events were rated as mild (78%) or moderate (22%) and none required medical intervention beyond a topical vaginal steroid cream for vaginal erythema and an antifungal cream/suppository for yeast infection. The majority of adverse events were experienced during the Fitting Period. There were substantially fewer occurrences in the Treatment Period and Optional Treatment Period once subjects were successfully fit with the device and entered treatment.

Effectiveness

The primary effectiveness analysis performed on the intent to treat (ITT) Cohort demonstrated that 79% of the 61 subjects reported at least a 50% reduction in FI episodes (95% CI 66-88%), which statistically exceeded the study's predetermined 40% threshold for success ($p < 0.0001$). Five (5) patients included in the ITT analysis were counted as treatment failures due to: unanalyzable diary data (2), exited due to unrelated health issues (2), and withdrew consent (1). In the Per Protocol (PP) Cohort, which included the 56 patients with fully analyzable diary data, 86% of subjects reported at least a 50% reduction in FI (95% CI 74-94%), also statistically exceeding the study's predetermined 40% threshold for success ($p < 0.0001$). Twenty-three (23) subjects (41% of the PP Cohort) reported a complete elimination of FI episodes during the Treatment Period. Seventy percent (70%) of subjects reported 75% or greater reduction in FI episodes.

The secondary endpoint of reduction in number of incontinent days was also found to be significant: patients experienced a reduction from incontinence on 49% of days to 11% of days (an average of 6.9 incontinent days in a 2-week period at baseline vs. 1.6 incontinent days during the 2-week treatment diary). Additionally, patients experienced a reduction in the mean number of FI Episodes per 2-week period from 11.6 ± 9.5 at baseline to 2.1 ± 2.9 during the Treatment Period.

Quality of Life

All subscales of the Fecal Incontinence Quality of Life (FIQOL) and the Modified Manchester Health Questionnaire (MMHQ) showed significant improvements. In response to a Patient Global Impression of Improvement (PGI-I) question that asked patients to "check the item that best describes how [their] control of bowel leakage is now, compared with how it was without the [insert]", 86% of patients selected "very much better" or "much better". Patients were also asked to list their most bothersome lifestyle restriction, and rank the impact that use of the Eclipse had on it. Of the 53 respondents to this question, 89% indicated that their most bothersome restriction was "completely addressed", or had been "helped a lot" (47% and 42%, respectively). Additionally, 98% (54/55) of patients responded that they would recommend the Eclipse System to a friend with FI. Finally, after completing the Treatment Period, 54/56 subjects (96%, PP Cohort) said the Insert was comfortable or they could not feel it (48% and 48% respectively); one subject reported the Insert was slightly uncomfortable, but tolerable; one reported the Insert was uncomfortable; and 0 patients reported the Insert was painful.

Optional Treatment Period

The treatment effect was maintained at the 3-month follow-up in the Optional Treatment Period for those that elected to continue use of the Eclipse System: 38 of 44 patients achieved treatment success (86.4%, 95% CI 73-95%). Significant improvements were also shown for clinical impact, comfort, and lifestyle, as measured by the FIQOL, MMHQ, and PGI-I scales, as well as subject satisfaction, comfort, and impact on lifestyle restrictions.

Table 4. Eclipse Insert, Trial Insert & Sizer: Sizes and Measurements				
Base Dimensions		Product ID		
Width (mm)	Length (mm)	Prefix SZ02-	Prefix EC02- (Eclipse) or TR02- (Trial)	
		Size (No Balloon)	Small Balloon (37x36mm)	Regular Balloon (47x42mm)
48	48	48RD	48RDS	48RDR
	51	48EP	48EPS	48EPR
51	51	51RD	51RDS	51RDR
	55.5	51EP	51EPS	51EPR
54	54	54RD	54RDS	54RDR
	57	54EP	54EPS	54EPR
57	57	57RD	57RDS	57RDR
	62	57EP	57EPS	57EPR
64	64	64RD	64RDS	64RDR
	70	64EP	64EPS	64EPR
70	70	70RD	70RDS	70RDR
	76	70EP	70EPS	70EPR
76	76	76RD	76RDS	76RDR
	83	76EP	76EPS	76EPR



Symbols Key



Caution



Non-Sterile



Lot Number



Rx-Only



Quantity



Refer to the Instructions for Use



Intended for single patient use only



Use By

- Also note that Sizers sold after Sep 2018 are directly marked with Ultra High Frequency RFID tags using ASCII text format and GS1 identifiers ((01) = the device's 14 digit Global Trade Identification Number, (10) = device Lot Number).
- U.S. Patents 8,740,766 & 8,740,767 & 9,072,578 & 9,289,278 & 9,707,067. Foreign Patents Pending.



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