

# Eclipse<sup>TM</sup> System

for bowel control in women

## UROLOGY & UROGYNECOLOGY

The Eclipse System is an innovative nonsurgical therapy that offers immediate results for women experiencing loss of bowel control.

The first vaginal Insert designed to provide bowel control, Eclipse is deliberately simple to use, non-surgical, immediately effective, patient controlled and clinic delivered.

### Why Eclipse?

- **Deliberately simple to use:** The Insert is placed like a tampon, diaphragm, or pessary and can easily be removed and reinserted by the patient.
- **Non-surgical and immediately effective:** Eclipse is clinically proven to work without risky surgery. With results similar to more invasive procedures, it can be used alone or concurrently with lifestyle modification, medication and/or to enhance the effectiveness of more invasive procedures.
- **Patient controlled:** The device doesn't need to be worn every day, all day. It can be for those times or occasions that a patient wants to feel more secure and confident, and avoid embarrassing accidents.
- **Clinic delivered:** The Insert, offered in a range of sizes, can be fit by practitioners (physicians or nurses) familiar with pelvic anatomy. Covered by Medicare, the reimbursement code is A4563.

### How it's used:

- The balloon is designed to control the patient's rectum and prevent stool from passing when they are not ready for it.
- Placed in the same location as a tampon, diaphragm, or pessary and can be removed at any time (fitting similar to pessary).
- A detachable Pump is used to inflate and deflate a balloon on the Insert.
- When ready for a bowel movement, the patient simply deflates the balloon; after the bowel movement, the balloon is inflated again.



- ▲ Non-surgical vaginally inserted rectal compression device to immediately restore bowel control by patients suffering from fecal incontinence (FI).

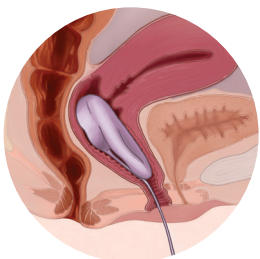
### Key components:

- **Insert:** A dual-layer balloon and base, available in multiple sizes
- **Pump:** Enables user to manually inflate or deflate the insert

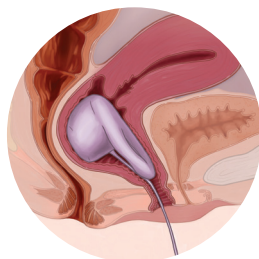
Note: The Pump is a separate device that detaches from Eclipse Insert when not in use. A Pump Regulator limits balloon pressure for optimal inflation.

In the LIBERATE study, incontinent women left the physician's office **continent**.

**84%** of patients reported effectiveness at 3 months (n=53/63).  
46% of patients had complete continence at 12 months (n=25/54).<sup>1</sup>



**Deflated device:**  
to allow bowel movements



**Inflated device:**  
to prevent stool leakage

## Ordering Information

CATEGORY	REORDER NUMBER	DESCRIPTION		
Sizer	SZ02-48RD, SZ02-51RD, SZ02-57RD, SZ02-64RD, SZ02-70RD, SZ02-76EP	Reusable sizing tool, representing the insert base. Intended to aid in selecting appropriate Trial Insert sizes. Sizers are only to be used in the clinical setting and are not intended to be taken home.		
Trial Insert – Small Balloon	TR02-48RDS, TR02-51RDS, TR02-57RDS	Single-patient-use vaginal Insert intended for in-office use during fitting and evaluation process. The Trial Inserts are identifiable by their white color.		
Trial Insert – Regular Balloon	TR02-48RDR, TR02-51RDR, TR02-57RDR, TR02-64RDR, TR02-70RDR, TR02-76EPR			
Eclipse Insert – Small Balloon	EC02-48RDS, EC02-51RDS, EC02-57RDS	Single-patient-use vaginal Insert intended for longer-term use (up to one year). The Eclipse Inserts are identified by their indigo color.		
Eclipse Insert – Large Balloon	EC02-48RDR, EC02-51RDR, EC02-57RDR, EC02-64RDR, EC02-70RDR, EC02-76EPR			
Pump	PP02	The Pump is used by the patient for inflating and deflating the Insert Balloons. The Pump is packaged with the medium Regulator and a Patient Instructions For Use Booklet.		
Valve (5 each per pack)	VV04	Each Insert is packaged with a Valve. A replacement Valve will be provided to a patient in the case of damage or irreversible soiling of the Valve on their Insert.		
Regulator (5 each per pack)	RR02-LOW, RR02-MED, RR02-HIGH	The medium Regulator is provided with the Pump. The low or high Regulator can be used to provide lower or higher maximum balloon pressure levels.		
Extension Tube (5 each per pack)	TT02	Additional tubing to be used as needed to customize the Tube length insert.		
Utility Cart	ECLCRT01	4-drawer storage Cart to hold Eclipse products and patient materials		
Quick Start Kit (one time purchase)	ECLBDL01: Base Kit	BASE KIT Only (ECLBDL01) (No Eclipse Inserts)	5-Pack QSK (ECLBDL04)	14-Pack QSK (ECLBDL03)
	ECLBDL04: 5-Pack Kit	Includes: Sizers (11 Sizers – 2 each except 1 of the largest) Trial Inserts (14 Inserts – all 9 sizes plus extra of common sizes) Pump (3 Pumps) Accessories (5 each of the following: Valves, Extension Tubes, Regulator – low pressure, Regulator – high pressure) Utility Cart	Includes: <b>BASE KIT plus 5 Eclipse Inserts</b> (one each of the most common sizes) • 1 each: EC02-48RDR, EC02-51RDR, EC02-57RDR, EC02-64RDR, EC02-70RDR	Includes: <b>BASE KIT plus 14 Eclipse Inserts</b> (all 9 sizes plus extra of the common sizes) • 1 each: EC02-48RDS, EC02-51RDS, EC02-57RDS, EC02-76EPR • 2 each: EC02-48RDR, EC02-51RDR, EC02-57RDR, EC02-64RDR, EC02-70RDR
	ECLBDL03: 14-Pack Kit			
5-Pack of Eclipse Inserts and Pumps (special re-order bundle discount)	ECLBDL05	Re-order Eclipse Inserts in quantities of 5 to receive bundle discount Account selects sizes of Eclipse Inserts for 5-pack re-order bundle (includes 5 Pumps (PP02))		
Eclipse Evaluation Program		Laborie representative delivered product and case support to evaluate Eclipse System on a limited number of patients. Pricing pre-defined for the Trial Insert fitting and Eclipse Insert fitting inclusive of necessary accessories		

### References

1 Richter HE, Dunivan G, Brown H, et al. A 12-Month Clinical Durability of Effectiveness and Safety Evaluation of a Vaginal Bowel Control System for the Nonsurgical Treatment of Fecal Incontinence. Female Pelvic Med Reconstr Surg. 2019; 25:113-119.

Please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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