

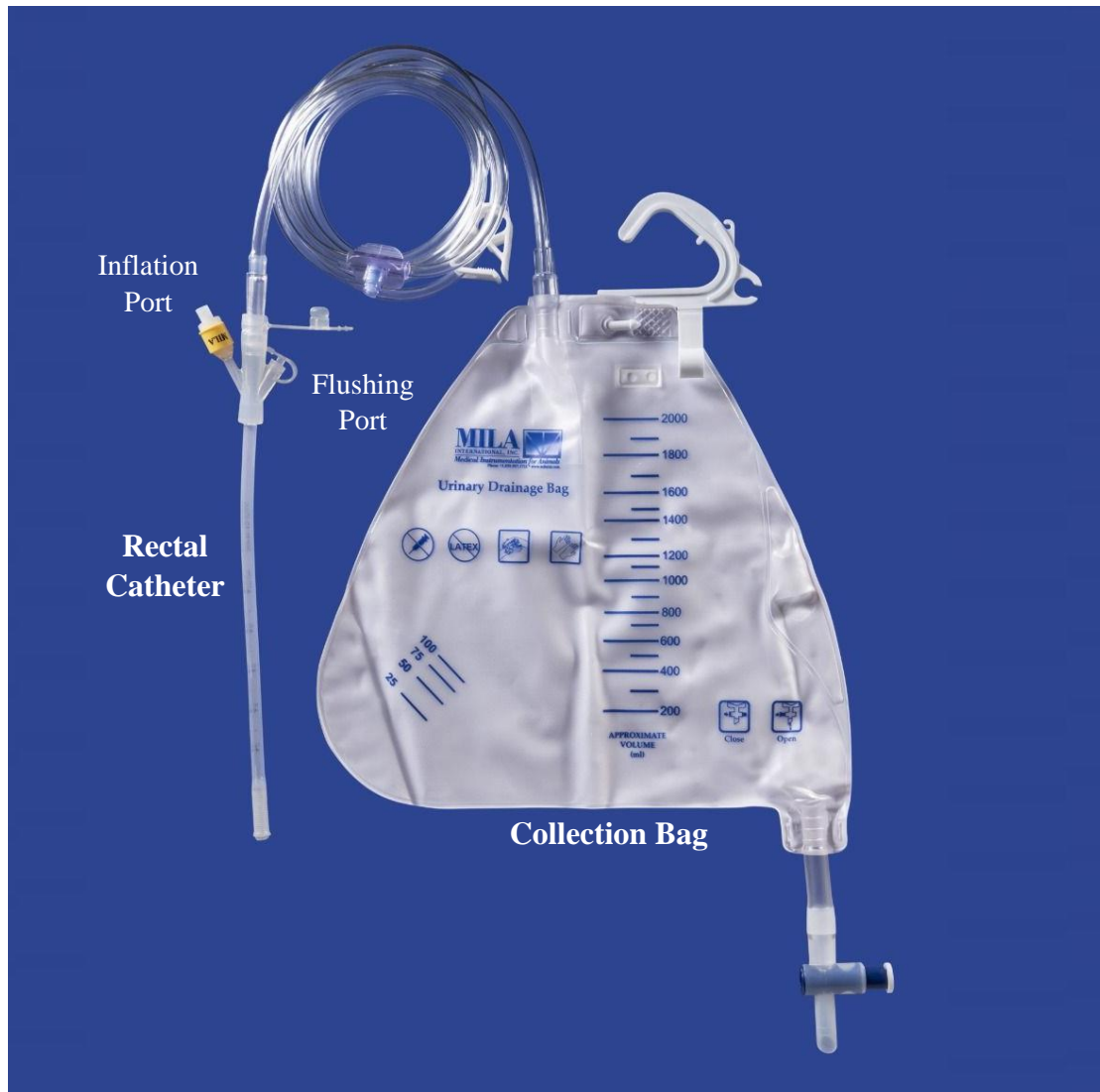


## Instructions for Use

Rev. 10/29/2024

# Fecal Management System

*Closed collection system for the management of intractable diarrhea in dogs.  
Includes a silicone rectal catheter with retention balloon and a 2L collection bag.*



## Indications for Use

The MILA Fecal Management System (FMS) is for the management of intractable diarrhea and liquid fecal incontinence in dogs.

## **Contraindications**

Suspected or confirmed rectal or anal tumor	Silicone allergy or sensitivity
Indwelling rectal thermometer	Any anorectal injury or defect
Recent anorectal surgery	Rectal or anal strictures or stenosis
Suspected or confirmed rectal mucosal impairment such as severe or ischemic proctitis or mucosal ulcerations	

## **Potential Complications**

Leakage of stool around the balloon and catheter	Temporary loss of anal sphincter muscle tone
Rectal or anal bleeding	Infection
Catheter blockage	Bowel obstruction
Perianal skin breakdown	Perforation of the bowel
Pressure necrosis or ulceration of rectal and/or anal mucosa	

## **Supplies Needed**

(not included)

Exam gloves	Water-based or 2% lidocaine lubricant
20mL luer-lock or slip-tip syringe	Elizabethan (“E”) collar

**Refer to this symbol, , for additional warnings and precautions throughout the instructions.**


## ***Instructions***

Read through all steps before the procedure.

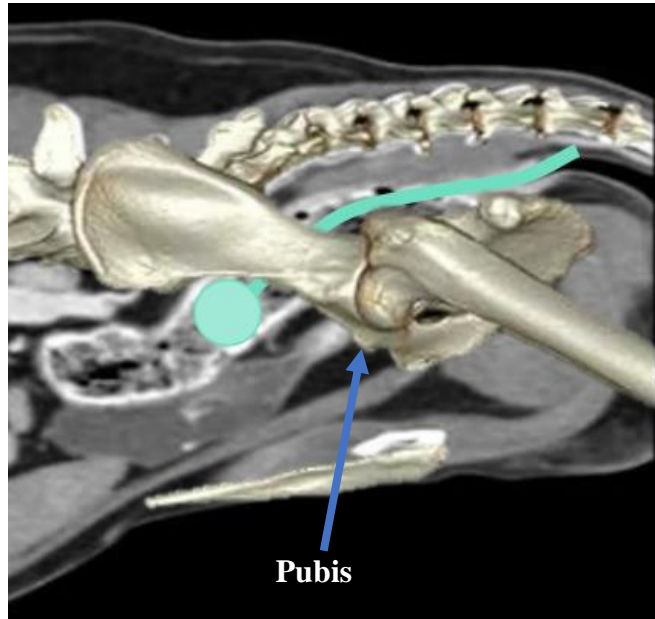
## ***Preparation***

1. Prior to placement, test the retention balloon by inflating it to approximately the size of the patient's normal stool. The maximum volume of the balloon can be found on the inflation hub. Note the volume of air used and then deflate the balloon.
2. Perform a digital rectal exam to evaluate for contraindications for use.  
**TIP:** Application of 2% lidocaine lubricant to the perineal area and rectum prior to procedure may ease placement.
3. Position the patient in left lateral recumbency. If the patient is unable to tolerate this position with minimal movement, restrain otherwise to allow access to the rectum.

## ***Rectal Catheter Placement***

4. Connect the collection bag to the catheter or close the catheter by inserting the tethered plug. Apply a small amount of water-based lubricant to the balloon end of the catheter.  
 **Excessive lubricant can cause the catheter to slip out.**
5. Grasp the catheter at the balloon and gently introduce the catheter into the anus until it is advanced to the level of the colon.

6. Inflate the balloon with the predetermined volume of air.  
**⚠ The balloon should be inflated with AIR only. In the event that the FMS is removed with the balloon inflated, the balloon will be more compressible if filled with air than with water.**
7. To ensure that the balloon is not inflated within the pelvic canal, gently pull the catheter until slight resistance is felt (indicating the balloon is against the pubic bone).
  - *If the patient appears uncomfortable (e.g., appears to be straining to defecate), deflate the balloon and reinflate with less air.*



8. Carefully open the catheter by removing the tethered plug and immediately connect the drainage line and collection bag assembly  
**⚠ Keep the bag positioned lower than the patient to allow gravity to facilitate drainage.**
9. Place an Elizabethan collar on the patient to prevent catheter removal.
10. Document catheter placement in the patient's medical record (see page 5).

## ***Catheter Maintenance and Tips for Use***

- Observe the Fecal Management System (FMS) at regular intervals to check for obstruction in the collection line due to kinks, solid waste, or external pressure.
- Check the retention balloon every 4-6 for any loss of air.
  - Hold the catheter in place and withdraw the air from the balloon with a luer lock or slip-tip syringe.
  - If the volume is less than when originally placed, reinflate to the original volume.
- To ensure unobstructed flow, the catheter may be flushed using the irrigation port. This can be performed on a regular schedule or as needed.
- Restrict patient movement when not directly supervised to prevent catheter dislodgement.
- Change collection bag as needed. Dispose of medical and infectious waste per hospital protocol.

## ***Irrigation***

1. Empty the collection bag.

2. Using a luer-lock or slip-tip syringe, slowly flush warm water into the irrigation port.
  - ⚠ Only use the irrigation port to flush the catheter.
  - ⚠ Do not attempt to evacuate through the flushing port.
3. Observe the collection line and bag for drainage.
  - ⚠ If blockage occurs due to solid waste, discontinue use of the FMS. Semi-formed or solid stool cannot pass through the catheter and may cause occlusion, which can result in harm to your patient.
  - ⚠ Patient position can affect the irrigation process and flow. For best results, keep the collection bag below the patient.
  - ⚠ If repeated attempts to flush the catheter fail to return the flow of liquid waste, remove the FMS and inspect all parts for obstruction. Reevaluate the patient to determine if replacement is warranted.
4. Empty the collection bag.

## **Removal**

⚠ Remove the FMS immediately if any signs of rectal bleeding or trauma occur.

1. Deflate the retention balloon entirely using a luer lock or slip-tip syringe.
2. Grasp the catheter as close to the patient as possible. Slowly and gently pull to remove.
3. Dispose of the catheter and collection bag per hospital protocol.
  - ⚠ The Fecal Management System is a single-use device and should not be reused.

*DISCLAIMER: These instructions are for supplemental education and guidance only and do not substitute professional veterinary medical advice.*

### ***Questions or comments?***

Call us at 859-957-1722 or 888-645-2468  
Monday-Friday 9am-5pm EST

or email us at [ProductSupport@milaint.com](mailto:ProductSupport@milaint.com)

## Fecal Management System Placement Record

*Place or transcribe into the patient's medical record.*

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_:\_\_\_\_ am pm

Patient Name: \_\_\_\_\_ ID Number: \_\_\_\_\_

Owner: \_\_\_\_\_ Veterinarian: \_\_\_\_\_

Indication for FMS: \_\_\_\_\_

Placed by: \_\_\_\_\_

Catheter Size: ☐ 20Fr ☐ 24Fr ☐ 28Fr MILA Lot number: \_\_\_\_\_

Inflation Volume: \_\_\_\_\_ml of air Empty/quantify orders in treatment plan: ☐ q \_\_\_\_ h

Date(s) and time(s) bag replaced: \_\_\_\_\_



Infectious? YES NO







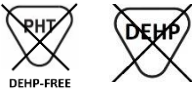








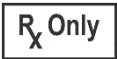




Chemotherapy Hazard? YES NO

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Removed by: \_\_\_\_\_ Date & time: \_\_\_\_\_

Reason/cause for removal: \_\_\_\_\_

# SYMBOL GLOSSARY

	Batch code/ Lot number
	Caution
	Consult instructions for use
	Contains or presence of phthalate DEHP
	Date of Manufacture
	Does not contain natural rubber latex
	Does not contain phthalate DEHP
	Do not re-sterilize
	Do not reuse
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Non-pyrogenic
	Non-sterile
	Not MRI safe
	Prescription only
	Temperature limits
	Sterilized using ethylene oxide
	Sterilized using steam or dry heat
	Use-by Date