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Minnesota Medical Technologies MyMiracle® Fecal Incontinence Insert – Instructions For Use

Description:

The Fecal Incontinence Insert is a recto anal insert which is intended to assist adult patients (18 years and older) and caregivers in the management of fecal incontinence. The device is designed to help prevent involuntary leakage of fecal matter through the anal canal.

Intended Purpose:

The Fecal Incontinence Insert is a recto anal insert which is intended to assist adult patients, 18 years and older, and caregivers in the management of fecal incontinence. The device is designed to help prevent the involuntary leakage of fecal matter through the anal canal.

The single use medical device is inserted via the anus into the anal canal and rectum. The device engages with and conforms to the anorectal junction and the anal canal to control the accidental leakage of fecal matter.

Indications for use:

The Fecal Incontinence Insert is indicated for the management of Accidental Bowel Leakage (ABL) due to bowel incontinence. The rectal insert is designed for self-insertion to seal and help prevent the involuntary leakage of stool from the rectum.

Intended Users:

The Fecal Incontinence Insert is intended to be used by adult patients (18 years and older) and caregivers.

Patient Target Group (Target Treated Population):

Adults (18 years and older) with accidental bowel leakage.

Clinical Benefits:

The Fecal Incontinence Insert is designed to prevent involuntary leakage of fecal matter through the anal canal.

Performance Characteristics:

The Fecal Incontinence Insert conforms to the anorectal junction and anal canal to prevent accidental bowel leakage.

Contraindications:

The Fecal Incontinence Insert is contraindicated for use in the pediatric population.

The Fecal Incontinence Insert is contraindicated for use in patients with the following conditions:

- a. History of an anal fissure, Grade III-IV internal hemorrhoids, or thrombosed external hemorrhoids in the past 6 months
- b. Anal or rectal pain and/or rectal bleeding in the past month
- c. History of fecal impaction with overflow diarrhea in the past 6 months
- d. History of Ileo-anal pouch

Risks:

- Possible mild irritation or discomfort of the anus or anal canal
- Possible migration or displacement of the insert into the anal canal and rectum
- Unexpected expulsion

Sizing:

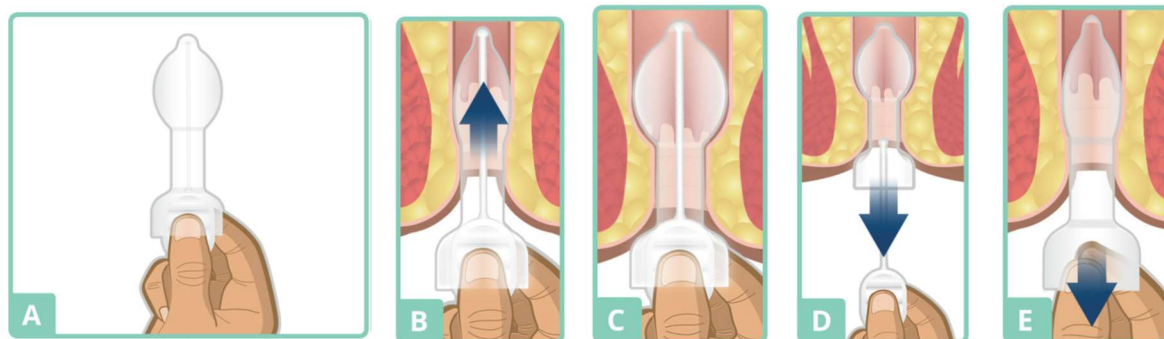
The Fecal Incontinence Insert comes in multiple sizes. It is recommended that you begin with the smallest size unless otherwise instructed by your physician. Upon engaging in daily activities, if you experience leakage or the device comes out unexpectedly, try a larger size.

Length of Wear:

The Fecal Incontinence Insert may be worn continuously for up to 24 hours. A single insert may be worn until your next bowel movement or changed as you see fit. After one insert has been expelled, you may replace it with another. Only one insert may be used at a time.

Insertion:

- Wash your hands.
- Open the Fecal Incontinence Insert package and remove the device.
- Place yourself in a relaxed, comfortable position, such as lying on a bed. Grasp the applicator and device retainer. (A) Align the device with the anus.
- Relax your muscles and gently insert the Fecal Incontinence Insert until the retainer rests on the anus (B) (C)
- Withdraw the applicator and discard the applicator and packaging with the normal trash (D)
- Wash your hands.



Removal:

The Fecal Incontinence Insert is designed so that it may be expelled with a normal bowel movement or manually removed. For convenience, it is recommended that the device be removed before a bowel movement. To manually remove:

- Grasp the external retainer and gently pull to remove the device. (E)
- Discard the device with the normal trash. Flushing of the device or device applicator is not recommended.
- Wash your hands.



Warnings, and Precautions:

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Fecal Incontinence may be medically treated. The Fecal Incontinence Insert is not intended to replace surgical options to treat accidental bowel leakage. Consult your physician for professional advice.

- This device is non-sterile and for single use only. Reuse of the device could result in device breakage.
- Do not use if the package is opened or damaged.
- Do not use if you have a silicone allergy.
- Do not use with suppositories.

Discontinue use of the Fecal Incontinence Insert and consult your physician if you have:

- Bloody stool or bleeding from the rectum
- Bleeding hemorrhoids
- Anal/rectal pain, irritation, spasms, tearing, or fissure
- Displacement of the Fecal Incontinence Insert into the anal canal or rectum which has not been expelled with the next bowel movement
- Undergone rectal surgery within the last 4 weeks.

Any serious reaction occurring when using the Fecal Incontinence Insert should be reported to the manufacturer and your local health authority.

SYMBOLS GLOSSARY:

 Rx Only	Caution: Federal law restricts this device to sale by or on the order of a physician
	Do not reuse
	Consult instructions for use
	Caution
	Do not use if package open or damaged
	Use by date
	Product reference number/Catalog number
	Manufacturer
	Authorized representative in the European Community
	Authorized representative in Switzerland
	European conformity
	LOT number
	Medical device
	Importer (EU)

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U.S. Pat. 10,959,822

Other Patents Pending

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