

## Navina Insert Product Information

### Product description

Anal plug.

### Shelf life and uses

The shelf life of the Navina Insert is 5 years.

The Navina Insert is a single use product and should only be used once before discarding.

### Material composition

**Insert Material:** Silicone elastomer, mineral oil, petrolatum

**Primary Package Material:** PE/Nylon

**Secondary Package Material:** Corrugated cardboard

### Intended use

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

Navina 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.

### Risks

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

### Warnings, Precautions, and Contraindications

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

- Navina Insert is contraindicated for use in the pediatric population.
- 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 open or damaged.
- **Do not** use if you have a silicone allergy.
- **Do not** use with suppositories.

### Discontinue use of Navina 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.



### Navina Insert

Reference	Type	Specification
6930400	Navina Insert Standard	Box of 30 pieces
6930500	Navina Insert Large	Box of 30 pieces
6930600	Navina Insert Starter Pack	Box of 5 Standard and 5 Large pieces

**Navina™** Insert



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