

## Product Care and Handling

1. Inspect the device before each use to ensure there is no damage to any of the components. Ensure the balloon and air release button are functioning properly. If there are any air leaks from the balloon, stop using it immediately.
2. The balloon is made from medical-grade silicone, chosen for its tensile strength, tear resistance, and durability. Most patients require only a few squeezes of the inflation bulb for effective relief. For added safety, the balloon is designed to withstand approximately 70 consecutive squeezes before failure.
3. After each use, follow the cleaning instructions. Cleaning is defined as the removal of all visible soil and contaminants from the Releve device.

## Cleaning Instructions

1. Releve should be cleaned before and after each use.
2. Wash the silicone balloon with warm water, mild or pH-neutral soap and dry. You can also use a pH-neutral wipe to clean the device.
3. Let the balloon dry completely before replacing the plastic guard.
4. Please do not submerge the entire device under water, as some components, such as the inflation bulb, are not waterproof.
5. Avoid using harsh chemicals or disinfectants to clean the silicone balloon as this can damage the silicone balloon.
6. If soiling occurs on the handle, wipe it with a wet cloth and dry completely before storing.
7. Store the device in a cool, dry location.

## Warning

- Releve is designed for use only during defecation and voiding.
- It should not remain inside the vagina for longer than 30 minutes.

## Precautions

- Releve is for single-patient use only. Do not share your device with others.
- Follow the cleaning instructions prior to first use
- Stop using the device immediately if you experience:
  - Unexplained bleeding, vaginal discharge, unpleasant odor, severe itching or pain.
  - Difficulty inserting the device into the vagina.
- Seek medical advice before using Releve if:
  - You are pregnant.
  - Your rectocele or other anatomy is visible outside the vagina or anus.
  - Use an IUD.
- Do not use if you have a sensitivity to silicone.
- Use only water-base lubricants with Releve.
- Do not wash Releve with products containing alcohol, acetone, or petroleum.
- Do not use Releve in other orifices other than the vagina.
- Prior to each use, ensure all components are working properly. If the balloon does not inflate, leaks air, or the air-release valve is not functioning correctly, stop using Releve immediately and contact Releve Customer Service.
- It is recommended that Releve be replaced every twelve (12) months.
- Contact your physician if prolonged or worsening symptoms occur.
- Releve is latex-free.

Questions? Visit the FAQs page on our website or contact us at [info@relevesupport.com](mailto:info@relevesupport.com).

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## Instructions For Use

Instructional video and FAQs available at  
[www.relevesupport.com](http://www.relevesupport.com)

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## Description

Releve is a vaginal device designed for short-term, manual support of the pelvic floor. It temporarily prevents the formation of posterior vaginal wall prolapse (rectocele) and other forms of pelvic organ prolapse (POP) that cause difficulty in emptying the bladder and bowels. Releve can be used as a replacement or supplement to digital manipulation and other vaginal support devices.

## Indications for Use

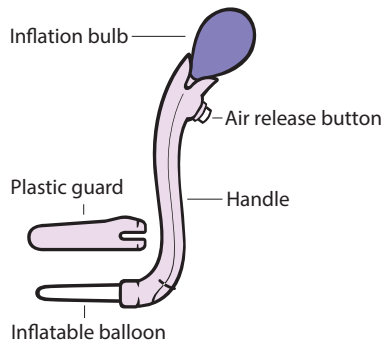
Releve® is indicated for the treatment of incomplete evacuation and voiding due to rectocele or cystocele in adult women.

## Contraindications

Releve should not be used by women with large rectoceles with permanent vaginal protrusion (Grade 3 or higher) or rectal prolapse. Women with active pelvic infections or open wounds in the tissue inside or surrounding the vagina should also avoid using Releve. Pregnant women should consult their physicians before use.

## Releve Components

Releve includes a medical-grade silicone balloon that inflates inside the vagina by squeezing the inflation bulb and deflates by pressing the air release button. The handle is used to aid in positioning and keep the balloon in place during use.



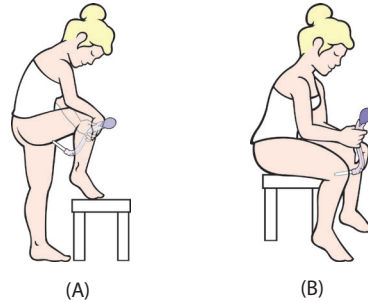
## How To Use

### Preparing Releve® for Use

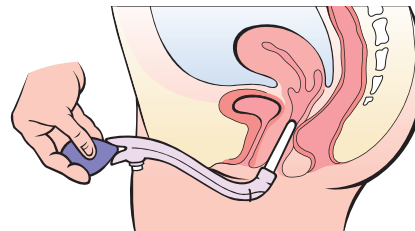
1. Prior to each use, ensure the balloon is clean and all components are working properly. If the balloon does not inflate, leaks air, or the air-release valve is not functioning correctly, stop using Releve immediately and contact Releve Customer Service.

### Inserting Releve®

**Important:** Ensure the silicone balloon is deflated before inserting or removing it from the vagina.

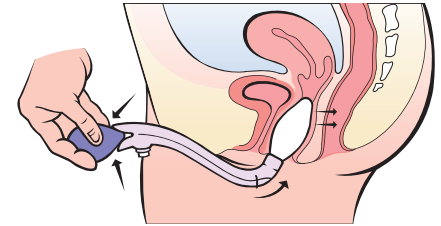


1. Find a comfortable insertion position. Some women find it easier to insert the product while standing with one leg on the commode (A), while others prefer to insert the device while seated on the commode (B).
2. Using a footstool to elevate your legs while on the commode may also be helpful.
3. If necessary, use a water-based lubricant to ease insertion of the balloon.
4. Insert the device until the silicone balloon is fully inside the vagina and no longer visible.



## Inflating Releve®

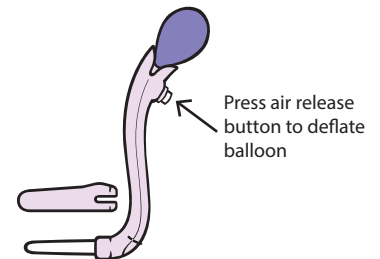
1. Once inserted into the vagina, squeeze the inflation bulb to inflate the balloon. Inflate as much as necessary until you feel the vagina is occupied by the balloon.



2. Use the handle to gently move the balloon into a position that facilitates a bowel movement. Use the handle to hold the balloon in place during use.
3. If you inflate the balloon to a size that causes discomfort, press the air release button on the back of the handle to reduce its size to a comfortable level.

## Deflating Releve®

1. To deflate the balloon, press down on the air release button on the back of the device.



2. Once fully deflated, remove the device from the vagina and follow the cleaning instructions.

## What is Included in the Box

- 1 each Releve® device
- 1 each Carrying bag
- 1 each Instructions for use