

## 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 leaks from the balloon, stop using it immediately.
2. 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 must be cleaned before and after each use.
2. Releve is NOT waterproof. DO NOT submerge the device in water or place the device under a faucet of running water.
3. Use a damp cloth to thoroughly wipe the Releve® balloon and handle with a mild or pH-neutral soap and warm water, or a pH-neutral wipe. DO NOT use a disinfectant to clean the device.
4. Wipe down Releve with a dry towel and let air dry completely before replacing the plastic guard or prior to use.
5. 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.




- Releve is not waterproof. DO NOT submerge the device under water or place the device under a faucet of running water.

## 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.
  - Pain or discomfort during use.
  - Difficulty inserting the device into the vagina.
- Seek medical advice before using Releve if:
  - You are pregnant or may become pregnant, or in a period following childbirth.
  - 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.
- Always clean Releve after each use by wiping the device and balloon with a clean, moist cloth and letting the device and balloon air dry.
- 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? Contact us at [info@relevesupport.com](mailto:info@relevesupport.com)

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## Instructions For Use

Instructional video 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

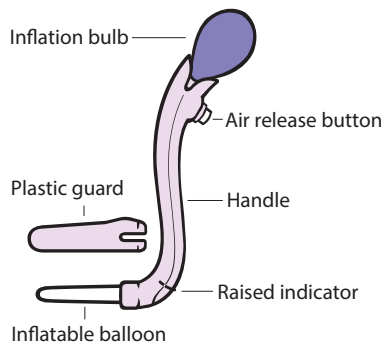
Releve® is indicated for the treatment of incomplete evacuation and voiding due to rectocele or cystocele in adult women.

## Contraindications

Releve should not be used by women with large rectoceles with permanent vaginal protrusion (Grade 3 or higher), rectal prolapse, or uterine 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 has a soft, 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

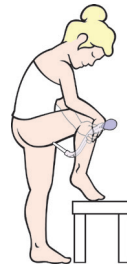
### Preparing Releve® for Use

1. Check that balloon and air release valve are functioning properly.

### Inserting Releve®

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

1. Find a comfortable insertion position. Some patients 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). Using a footstool to elevate your legs while on the commode may also be helpful.



(A)

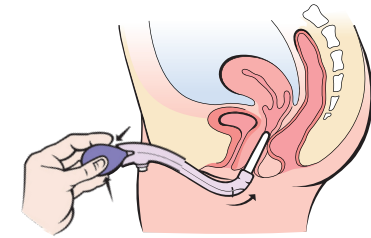


(B)

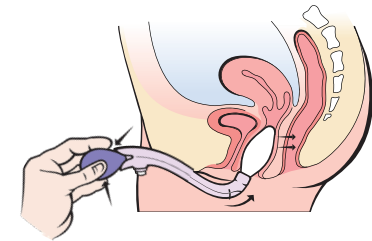
### Inflating Releve®

1. Insert the Releve device inside the vagina until the silicone balloon is no longer visible.
2. If necessary, use a water-based lubricant to ease insertion of the balloon.
3. 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.
4. If the balloon becomes overinflated, press the air release button on the back of the handle to reduce the size of the balloon.
5. Use the handle to gently move the balloon into a position that facilitates a bowel movement.
6. If you experience any pain during or after inflation, immediately deflate the balloon, remove it from the vagina, and contact your physician.

### Insert Releve while uninflated

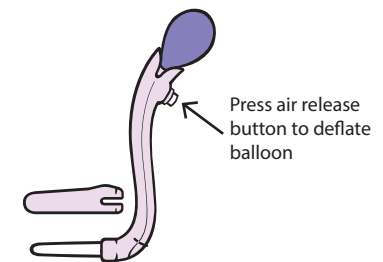


**Once inserted, squeeze the inflation bulb to inflate the balloon. The air release button is located on the back of the handle.**



### 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 Plastic balloon guard
- 1 each Carrying bag
- 1 each Instructions for use