

Contraindications:

- Large rectoceles with permanent vaginal protrusion (Grade 3 or higher)
- Rectal prolapse
- Uterine prolapse

Caution:

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 device:

- If you are pregnant or may be pregnant, or in a period following childbirth.
- If rectocele or other anatomy is visible outside the vagina or anus.

It is recommended that the product be replaced every twelve (12) months.

Warnings:

1. Do not use the Releve device in the anus/anal canal or the rectum, as it could cause injury.
2. It is mandatory to use a new Disposable Cover with each new use of the Intravaginal Balloon to prevent cross contamination between uses. **DO NOT USE THE INTRAVAGINAL DEVICE INSIDE THE VAGINAL CAVITY WITHOUT A DISPOSABLE COVER.**
3. The Releve device is designed for use during defecation only and should not remain inside the vagina for longer than 30 minutes.
4. Always clean the Intravaginal Support device after each use by wiping the device and balloon with a clean moist cloth and let the device and balloon air dry.
5. Because the Releve device is not watertight, **DO NOT** submerge the device under water or place the device under a faucet of running water.
6. Replace the Releve device if the device's balloon or check valves malfunction.
7. The Releve device is a single-patient reusable device that should be replaced yearly.

Manufactured for:
Surgin, Inc.
Scottsdale, AZ 85255 USA

S1002 Releve IFU Rev B | 0220 | © Surgin, Inc.



Instructions For Use

Intravaginal Support Device for Treatment of Rectocele and Obstructed Defecation (OD)

Please read carefully before using.

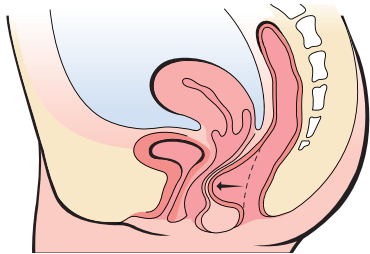
Instructional video available at
relevesupport.com

Indications for Use:

Releve® is indicated for the treatment of rectocele and obstructed defecation (OD) in adult women.

What is Rectocele and Obstructed Defecation?

A rectocele is caused by the weakening of the wall between the vagina and rectum. This weakened wall can bulge into the vagina and cause a bowel obstruction, leading to excessive straining and a feeling of incomplete evacuation. Improving the strength of this rectovaginal wall will prevent prolapse and facilitate a complete bowel movement.

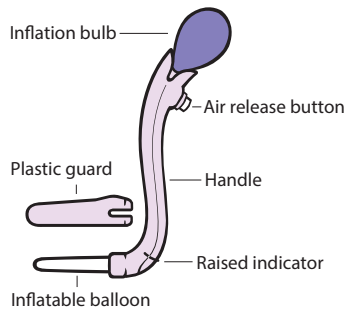


Arrow shows rectocele bulging into vagina

About Releve®

Releve is designed for use as a short-term, manual, removable and reusable device placed in the vagina to support and realign the pelvic floor to treat posterior vaginal wall prolapse (rectocele) and other causes of obstructed defecation.

Releve is intended to supplement or replace digitalization and other vaginal support devices.



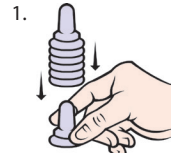
Releve includes a soft, guideable silicone balloon that inflates to occupy the vagina. The inflated balloon provides support to the vaginal wall to prevent rectocele and other conditions that cause obstructed defecation.

Instructions for Use:

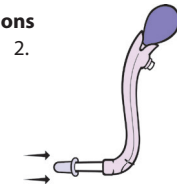
Preparing Releve® for Use

- Check that balloon and air release valve are functioning properly.
- Place a clean disposable cover over the Releve balloon before inserting into the vagina.

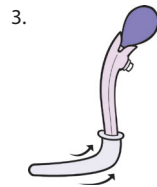
Disposable Cover Instructions



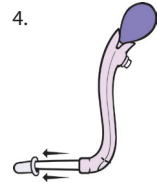
1. Remove new cover from bottom of stack.



2. Place cover on end of deflated balloon.



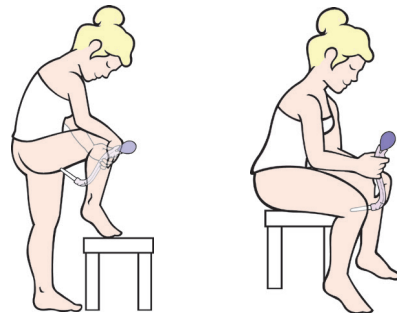
3. Roll cover over balloon until it reaches raised marker on handle.



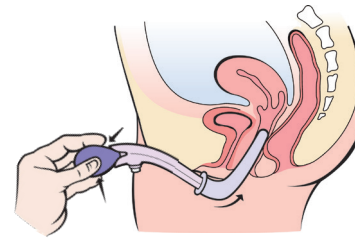
4. After use, deflate balloon, then remove and discard cover.

Inserting Releve®

- **Important:** Releve balloon should be deflated before inserting and before removing the device from the vagina.
- Find a comfortable insertion position. Some patients find it easier to insert the product while standing, or with one leg on the commode. Other patients prefer to insert the device while seated on the commode.

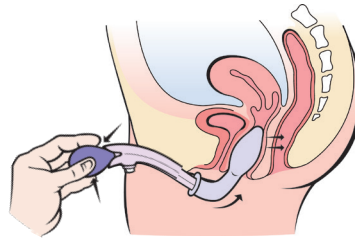


- The Releve device should be inserted inside the vagina until the balloon is no longer visible.
- If necessary, use a lubricant such as Aquaphor on the disposable cover to ease insertion of the balloon.



Inflating Releve®

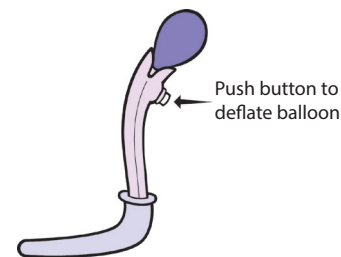
- Once inserted into the vagina, squeeze the inflation bulb to inflate the balloon.
- Inflate as much as necessary until you feel the vagina is occupied by the balloon.



- If the balloon becomes overinflated, press the air release button on the back of the handle to reduce the size of the balloon.
- If you experience any pain during or after inflation, immediately deflate the balloon, remove from the vagina and contact your physician.
- Use the handle to gently move the balloon into a position that facilitates a bowel movement.

Deflating Releve®

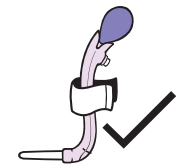
- Deflate the balloon by pressing down on the air release button on the back of the device.
- Once fully deflated, remove device from vagina and follow cleaning instructions.



Cleaning Instructions:

These cleaning instructions are indicated for use with the Releve device. Cleaning is defined as the removal of all visible soil and contaminants from the Releve device. The Releve device must be cleaned after every use.

1. Clean immediately after each use.
2. Use a soft, slightly damp, cloth to thoroughly wipe the Releve® balloon and handle after each use.
3. Use soap and warm water or a sterile wipe to remove any bodily fluids on the device.
4. Because the device is not watertight, **DO NOT SUBMERGE THE DEVICE UNDER WATER OR PLACE THE DEVICE UNDER A FAUCET OF RUNNING WATER.**
5. Always air dry the device thoroughly after each cleaning.
6. Store the device in a cool, dry location. Repeat cleaning instructions before and after each use.
7. **DO NOT** use a disinfectant to clean the device.



Product Care and Handling:

Before each use:

- Inspect the device to ensure there is no damage to the device or any components of the device.
- Ensure balloon and air release button are functioning properly.

After each use:

- Remove and discard the disposable balloon cover.
- Follow cleaning instructions.

Contents:

- 1 each Releve® Intravaginal Support Device and plastic guard
- 1 each Carrying bag
- 1 each Instructions for use
- 1 box Disposable balloon Covers