

Product Care and Handling

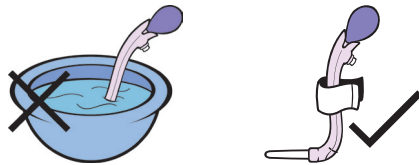
Inspect the device before each use to ensure there is no damage to any components. Ensure the balloon and air release button are functioning properly. If there are any leaks in the balloon stop using immediately.

After each use remove and discard the disposable cover and follow device cleaning instructions.

Cleaning Instructions

Cleaning is defined as the removal of all visible soil and contaminants from Releve. Releve must be cleaned before and after each use.

- Wash Releve before and after each use.
- Releve is NOT waterproof. DO NOT submerge the device in water or place the device under a faucet of running water.
- Use a damp cloth to thoroughly wipe the Releve® balloon and handle with a mild or pH-neutral soap and warm water. DO NOT use a disinfectant to clean the device.
- Wipe Releve down with a dry towel and let air dry completely before replacing the plastic guard or prior to use.
- Store the device in a cool, dry location.



Warning

- DO NOT use Releve without a new disposable cover. Failure to use a new disposable cover during each use could increase risk of cross contamination and vaginal infection.
- Releve is designed for use during defecation and voiding only and 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 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 nitrile or 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 let 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 Customer Service.
- It is recommended that Releve be replaced every twelve (12) months.
- Contact your physician if prolonged or worsening symptoms occur.

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



Instructions For Use

Instructional video available at
relevesupport.com

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

Important: Always use a new disposable cover during each use to prevent cross contamination that could lead to infection.

relevesupport.com

Description

Releve is a vaginal device used for short-term, manual support of the pelvic floor. It is designed to temporarily prevent the formation of posterior vaginal wall prolapse (rectocele) and other forms of pelvic organ prolapse (POP) during defecation and voiding. Releve can be used as a replacement or supplement to digital manipulation and other vaginal support devices.

Indications for Use

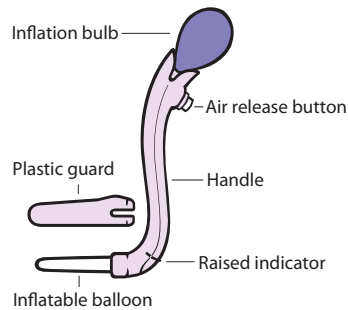
Releve® is indicated for the treatment of rectocele and obstructed defecation (OD) in adult women.

Contraindications

Women with large rectoceles with permanent vaginal protrusion (Grade 3 or higher), rectal prolapse, or uterine prolapse. Women with active pelvic infections or women who have open wounds in the tissue inside or surrounding the vagina. Women who are pregnant should consult their physicians prior to use.

Components

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 forms of pelvic organ prolapse that cause difficulty emptying the bowels and bladder.



Contents

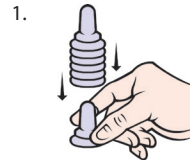
- 1 each Releve® Intravaginal Support Device
- 1 each Plastic balloon guard
- 1 each Carrying bag
- 1 each Instructions for use
- 1 box Disposable balloon covers (30 each)

Instructions for Use

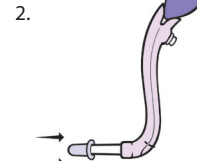
Preparing Releve® for Use

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

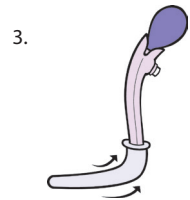
Disposable Cover Instructions



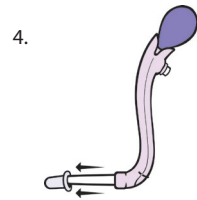
Remove new cover from bottom of stack.



Place cover on end of deflated balloon.



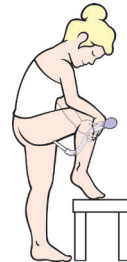
Roll cover over balloon until it reaches raised marker on handle.



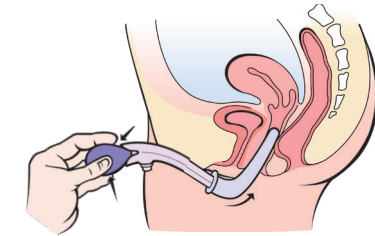
After use, deflate balloon, then remove and discard cover.

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.

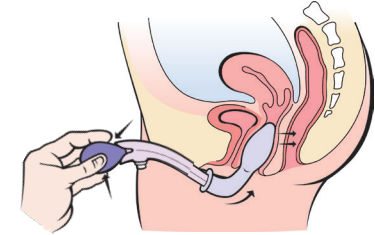


- The Releve device should be inserted inside the vagina until the balloon is no longer visible.
- If necessary, use a lubricant such as Aquaphor on the disposable cover to ease insertion of the balloon.



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.



- Use the handle to gently move the balloon into a position that facilitates a bowel movement.
- If you experience any pain during or after inflation, immediately deflate the balloon, remove from the vagina and contact your physician.

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.

