

Intended Use

Releve® is intended to provide temporary vaginal support during toileting for women experiencing incomplete bowel or bladder evacuation due to pelvic organ prolapse.

Indications for Use

For adult women with incomplete bowel or bladder evacuation caused by rectocele, cystocele, or similar forms of pelvic organ prolapse.

Contraindications

Do not use Releve if:

- You have an advanced rectocele with vaginal tissue protruding beyond the vaginal opening.
- You have rectal prolapse
- You have an active pelvic infection or open wounds in or around the vagina
- You are pregnant, unless advised by your healthcare provider

Warnings and Precautions

- This device is supplied non-sterile and must be cleaned before first use.
- For vaginal use only. Do not insert in other orifices.
- Do not share: single-patient, multiple-use
- Use only water-based lubricants
- Do not use if you are sensitive to silicone
- Do not leave in for longer than 30 minutes
- Stop use and contact your physician if you experience unexpected bleeding, unusual odor, persistent pain, or difficulty inserting.
- Contact your physician for persistent symptoms
- Replace every 12 months
- Consult your healthcare provider before use if you are uncertain whether this product is right for you.

Manufacturer & Regulatory Contacts

Manufactured for:

Surgin Inc.
16443 N. 91st Street, Suite 107
Scottsdale, AZ 85255 USA
info@relevesupport.com

Questions?

For support, visit our FAQ page or email us at info@relevesupport.com.

Regulatory Compliance Statement

Releve® is a single-patient, multiple-use, non-sterile medical device intended to provide temporary vaginal support during toileting for women experiencing incomplete bowel or bladder evacuation due to pelvic organ prolapse.

This device conforms to applicable regulations in the following regions:

- United States: Complies with FDA 21 CFR 801 (Class I)

In case of a serious incident, contact Surgin Inc. and notify the competent authority in your country.

Symbols Used



Consult Instructions for Use



Single-patient, Multiple-use



Manufacture Date



Manufacturer



Non-sterile



Lot number



Reference number



Medical Device



Not made with natural rubber latex



Vaginal Support Device Instructions for Use

Document ID: S1002 | Rev G | 0825

Video instructions & FAQs available at:
relevesupport.com

Electronic Instructions for Use (eIFU) also
available online

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What's in the Box:

Your Releve Kit Includes:

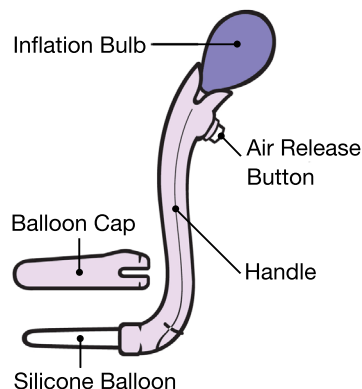
- 1 Releve® device
- 1 Carrying bag
- 1 Instructions for Use

Device Description

Releve® is a vaginal support device designed to assist with bowel and bladder emptying by temporarily supporting the vaginal wall during toileting. This helps reduce symptoms caused by pelvic organ prolapse, such as rectocele or cystocele.

Components:

- Inflatable silicone balloon
- Balloon cap
- Inflation bulb
- Air release button



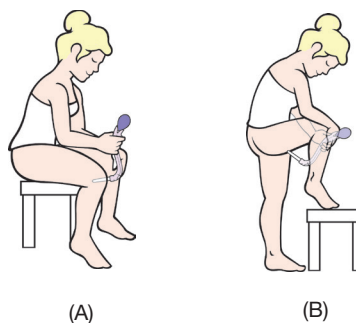
How to Use Releve

Preparing for Use

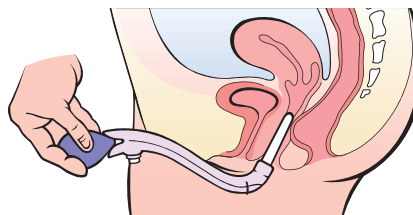
1. Before use, remove the balloon cap and save it for storage between uses.
2. Inspect device before each use. Ensure balloon and valve are functioning properly.
3. Clean the balloon with warm water and mild or pH-neutral soap.
4. Ensure the balloon is fully deflated before insertion.

How to Use Releve (continued)

Inserting Releve

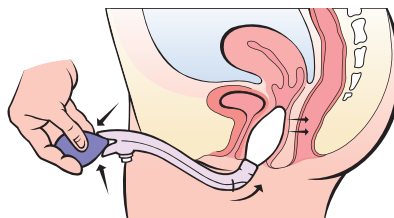


1. Choose a comfortable position — either seated (A), or standing near the commode with one foot elevated (B).
2. Use a footstool if helpful.
3. Apply water-based lubricant if needed.
4. Gently insert the uninflated balloon until it is fully inside the vagina and no longer visible.



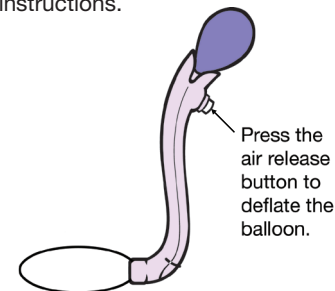
Inflating the Balloon

1. Once inserted, squeeze the inflation bulb until the balloon feels comfortably secure inside the vagina - typically 3-5 squeezes. Use more or less if necessary.
2. Hold the handle to keep the balloon inside the vagina during use. Use the handle to adjust balloon position to facilitate a bowel movement.
3. If discomfort occurs, press the air release button on the back of the handle to reduce balloon size.



Deflating & Removal

1. Before removal, deflate the balloon by pressing the air release button on the back of the device until all of the air is released.
2. **Important:** Do not block the area around the button, as air escapes around the sides of the button.
3. After deflation, gently remove the device and follow the cleaning instructions.



Troubleshooting Tips

1. **If the balloon won't inflate:** Check that the bulb and balloon are not damaged and that the air release button is not pressed.
2. **Balloon deflates slowly or does not fully deflate:** Make sure the air release button is fully pressed and that the area around the button is not blocked, as air escapes around the sides of the button.

Cleaning and Storage

- Clean before and after each use.
- Wash balloon with warm water and a pH-neutral or mild soap like SoftSoap®.
- Let the balloon dry completely before storing or replacing the balloon cap.
- Avoid submerging the handle or bulb in water, as these components are not sealed.
- Do not use boiling water or dishwasher to clean the device.
- Do not use alcohol, acetone, petroleum-based, or abrasive cleaners on the balloon.
- If the handle becomes soiled, wipe it with a damp cloth and dry fully.