



# INSTRUCTIONS FOR USE

## INDICATIONS FOR USE

The Renew® Insert is indicated for the management of Accidental Bowel Leakage (ABL) due to bowel incontinence. The Renew Insert is designed for self-insertion to seal and help prevent the involuntary leakage of stool from the rectum.

## DESCRIPTION

Renew Inserts are made of soft silicone and are safe and comfortable to use in the rectum. Renew Inserts and the removable applicator are both single-use and non-sterile. Renew Inserts are available in 2 sizes: Regular and Large.

### Possible Side Effects May Include:

False urge to empty your bowels.  
Mild irritation of anal area.

### Warnings and Precautions

Bowel incontinence may be medically treated. The Renew Insert is not intended to replace surgical options to treat ABL.

Consult your doctor for professional advice.

Do not use if you have an allergy to silicone.  
Do not use with suppositories.

Discontinue using the Renew Inserts and consult your doctor if you experience the following:

- Bleeding hemorrhoids
- Rectal bleeding or bloody stool
- Anal/rectal pain, irritation, spasms, fissure or tearing
- Undergone rectal surgery within the past 4 weeks
- Displacement of the Insert upward into the anus and it is not expelled with the next bowel movement

Do not use if opened or damaged. Single use only. Non-sterile.

## US CLINICAL TRIAL SUMMARY

A clinical study has shown that Renew Inserts are safe and work as directed. Three sites enrolled 97 subjects in this study. Safety data were analyzed on 91 treated subjects who used Renew Inserts. Reduction in the frequency of Accidental Bowel Leakage (ABL) episodes was measured by comparing pre- and post-treatment results on 85 subjects who used the Renew Insert for at least 1 week or more during the 12-week Treatment Period. Reduction in the Wexner Score (an assessment of bowel incontinence) was analyzed on 77 subjects who had both a pre- and post-treatment Wexner score.

### Benefits

The clinical study demonstrated that the Renew Insert helps prevent Accidental Bowel Leakage, delivering the following benefits:

- A median reduction of 81.8% in the frequency of ABL episodes
- Over 91% of the Renew Insert users demonstrated a ≥ 20% reduction in ABL episodes
- A median reduction of 29.4% in the Wexner score
- Overall satisfaction among the majority of Insert users was high, with 91.4% rating the overall experience and ease of use as a 9.5 (median) on a 10 point scale

### Risks

There were no reported severe, serious or unanticipated adverse events. Almost all (98.7%) of the adverse events possibly related to the Renew Insert were rated as ‘mild’ and included the sensation of urge, irritation or soreness around the anal area.

Displacement of the Insert may occur when the lower (bottom) disk of the Insert becomes temporarily displaced and moves upward into the anus.

Displacements of the Insert were reported by 23.9% of the study participants. Instances of displacement of the Insert were resolved predominately by natural expulsion during subsequent bowel movements.

# FREQUENTLY ASKED QUESTIONS

## 1. Have Renew® Inserts been clinically tested?

Yes. Clinical studies in the USA have demonstrated that the Renew Inserts are safe and reduce accidental bowel leakage by 81.8%\*.

## 2. Are Renew Inserts comfortable to insert and wear?

Yes. Clinical studies show Renew Inserts are: soft, fit the contours of the body, comfortable to wear and easy to use\*. Inserting a Renew Insert properly will not cause discomfort. Just follow the step-by-step instructions.

## 3. How do I know when the Renew Insert is properly in place?

When the Renew Insert is properly in place, the top disc is resting just inside the rectum and the bottom disc is just outside the anus. You should not feel any discomfort.

## 4. How long can I wear a Renew Insert?

Renew Inserts may be worn continuously, day and night. A single Renew Insert can be worn until your next bowel movement, or changed as desired. After one is expelled, you may replace it with a new Renew Insert. Never use more than one Insert at a time.

## 5. How do I know what size Renew Insert to use?

You should first use the Regular size Renew Insert. If you find that the Renew Insert comes out at unexpected times or if you experience leakage, try the Large size Renew Insert. If you experience discomfort, discontinue use.

## 6. What are some insertion positions?

You may want to sit on the toilet or try standing with one foot up on the toilet or squatting. You should use whichever insertion position is most comfortable for you. Avoid multiple insertion attempts to limit the exposure of stool to other parts of the body.

## 7. Can a Renew Insert get lost inside my body?

No. Clinical research has shown that Renew Inserts come out with a person’s next bowel movement\*. The Renew Insert is designed so the top and bottom discs hold it in place in the anal canal between the rectum and anus. In the unlikely event a Renew Insert moves into the anus, it will be naturally expelled with your next bowel movement.

## 8. What if the Renew Insert comes out when I go to the toilet and pass wind (gas) or urinate?

The Renew Insert is designed to be expelled with a bowel movement, but occasionally it may come out if you are sitting on the toilet and passing wind (gas) or urinating. If this happens, simply replace it with a new Renew Insert. If you are using a Regular size Renew Insert and this happens frequently, you may want to try the Large size Renew Insert.

## 9. Will I be able to pass wind (gas) with the Renew Insert in place?

Yes. The Renew Insert still allows for the passage of wind (gas). If you are using a Large size Renew Insert and feel discomfort from wind (gas), try a Regular size Renew Insert.

## 10. Can I bathe and be physically active when I’m wearing my Renew Insert?

Yes. You can do all of your activities while using a Renew Insert.

## 11. Should I flush the applicator and Renew Insert down the toilet?

Flushing of the applicator and the Renew Insert is not recommended.

\* U.S. Clinical Study (Renew 210 CLD).

## KEY TO SYMBOLS

	Manufacturer
	Do not use if package is open or damaged
	Authorized European Representative
	Catalog Number/Model Number
	Refer to Instructions for Use
	Do Not Reuse
	Lot Number / Batch Code
	Expiration Date
	Non Sterile
	CE Marking
	Dispose Properly
	Quantity
	Part Number
	Recycle
	Prescription Use US Only: CAUTION: Federal law restricts this device to sale by or on the order of a physician.



## SIZING

Renew® Inserts come in two sizes, Regular and Large. Start with the Regular size Renew Insert. If the Regular size comes out at unexpected times or if you experience leakage, try the Large size Renew Insert.



## PREPARATION

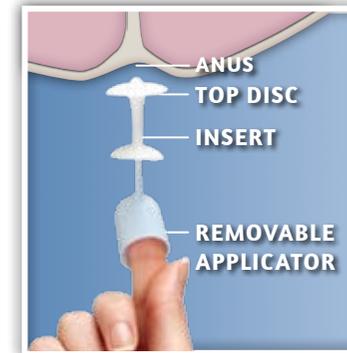
**Step 1.** Wash your hands. Separate a single blister unit by pulling sideways to break the perforations holding them together.



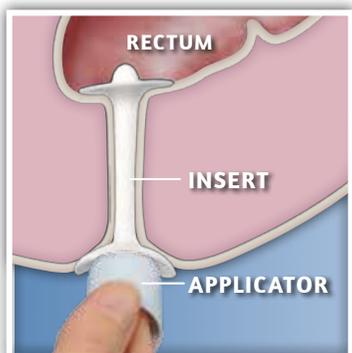
**Step 2.** Do not use a Renew Insert package unless it is fully sealed. Peel back the top of the package to fully expose the Renew Insert.



**Step 3.** Place your index finger into the light blue removable applicator and lift the Renew Insert out of its package. The Renew Insert is now ready to use. If the Insert falls off the applicator prior to insertion, discard it and use a new one.

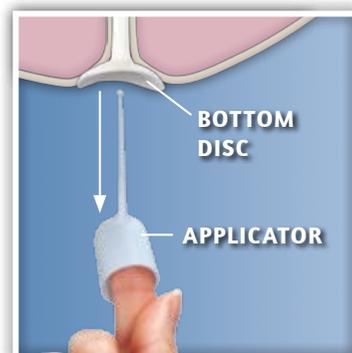


**Step 4.** Sit on a toilet. Raise yourself up onto one hip by leaning to the side. Reach behind your raised side and position the top disc of the Renew Insert so it's lightly resting on the anus.

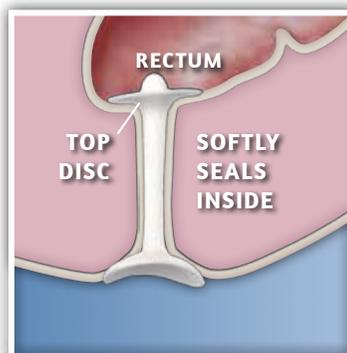


## INSERTION

**Step 5.** Relax your muscles and gently slide the Renew Insert into the anus until you feel the applicator touch the anus.



**Step 6.** Gently withdraw the applicator. The bottom disc of the Renew Insert should be resting just outside the anus.



**Step 7.** Discard the applicator in a waste receptacle. Wash your hands after use. The Renew Insert is now properly in place and sealing from the inside to help prevent ABL.

## REMOVAL

**Step 8.** The Renew Insert is designed to be naturally expelled with your next bowel movement. Alternatively, simply pull on the bottom disc outside the anus to remove the Renew Insert. Wash your hands after direct contact with the used Insert.

## REPLACEMENT

**Step 9.** For optimal protection, use a new Renew Insert after each bowel movement.

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