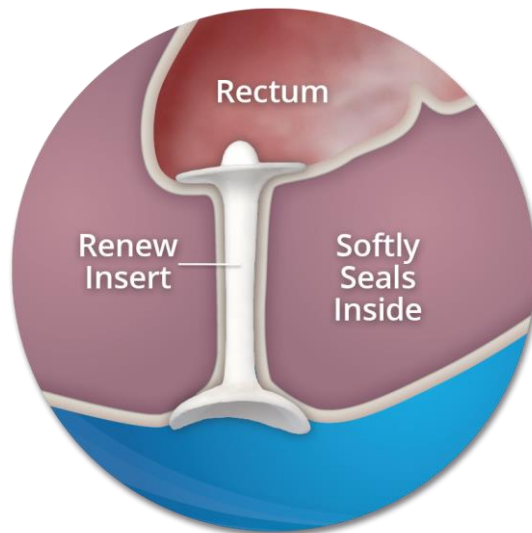




**FOR IMMEDIATE RELEASE**

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**Renew Medical introduces new device in the UK to help prevent Accidental Bowel Leakage**

*Renew Insert is a comfortable anal insert device for managing Accidental Bowel Leakage, giving patients confidence to live an active life.*

London, UK, 15 April 2015: Renew Medical UK is announcing the launch of the Renew Insert, an innovative silicone anal insert device that is now available on prescription for patients with Accidental Bowel Leakage (ABL) in the United Kingdom.

ABL is medically termed faecal or bowel incontinence. The Bladder and Bowel Foundation estimates that one in 10 adults will have problems with bowel control at some point in their lives.\* A majority of ABL sufferers report a severe quality of life disruption, yet only a small number of those affected (approximately one in 10) have obtained a clinical diagnosis.\*\*

The Renew Insert is a discreet, easy-to-use device that is designed for self-insertion to comfortably seal the rectum from the inside to help prevent Accidental Bowel Leakage. Renew Inserts are available on prescription in two sizes to fit a wide range of users and can be delivered by a Dispensing Appliance Contractor or collected from local chemists.

Clinical studies in the United States have demonstrated that the Renew Insert is safe to use and that the device reduces Accidental Bowel Leakage by nearly 82%.\*\*\* A consumer panel of Renew Insert has also rated overall satisfaction at 4.8 out of 5 after nearly three years of continuous use.\*\*\*\*

Carolynne Vaizey, consultant surgeon and Chair of Surgery at St Mark's Hospital and Academic Institute, London says: "These Renew Inserts provide a new non-surgical option for managing Accidental Bowel Leakage, as an alternative or as an adjunct, to invasive therapy. The Inserts may restore patients' dignity and provide them with the confidence to live a normal and active life."

The Renew Insert has CE mark approval in Europe.

—ENDS—

## Notes to editor:

### References

- \*<http://www.nhs.uk/livewell/incontinence/pages/breakingthetaboo.aspx>
- \*\*Nielsen Mature Women's Health Survey commissioned by Renew
- \*\*\*REST study, US Pivotal Clinical Study, Renew, 210CLD (submitted for publication)
- \*\*\*\*35 month UK Consumer Panel - MKT-008 Study

### About Renew Insert

The Renew Insert is a new product developed to allow people suffering from Accidental Bowel Leakage (ABL) to live a normal and active life. It is made of soft and flexible silicone and is suitable for use for women and men. The Renew Insert provides protection from solid and liquid stool leakage and is indicated for continuous use. Renew Inserts are designed for single-use and naturally expelled with a bowel movement.

### About the REST study

REST (A Study to Evaluate the Safety, Tolerability and Effectiveness of the Renew Insert in Treating Accidental Bowel Leakage) was a multicentre, prospective, single-arm, non-randomised pivotal study designed to establish the safety, effectiveness, and tolerability of the Renew Insert in patients with moderate-to severe bowel incontinence.

- Reduction in the frequency of ABL episodes was measured by comparing pre-and post-treatment results on 85 patients who used the Renew Insert for at least one week or more during the 12-week treatment period.
- The study showed a median reduction of 81.8% in the frequency of ABL episodes when the Renew Insert was used.
- There were no reported severe, serious or unanticipated adverse events. Nearly all (98.7%) of the adverse effects possibly related to the Renew Insert were rated as mild and included the sensation of urge, irritation or soreness around the anal area.
- The reported overall satisfaction among the majority of Insert users was high, with 91.4% rating overall experience and ease of use rated as a 9.5 (median) on a 10 point scale.

### About Renew Medical

Renew Medical is a privately-held continence-care company that is passionate about improving the lives of people suffering from ABL. We have researched, developed and clinically tested the Renew Insert for over seven years in the US and Europe. To learn more about Renew Medical, Inc, please visit: <http://renew-medical.uk>