SUMMARY OF CLINICAL RESEARCH

BACKGROUND

Management of Accidental Bowel Leakage (ABL), medically termed Faecal Incontinence (FI) remains challenging due to the limited availability of consistently safe, effective and/or tolerable treatment options.

OBJECTIVE

Evaluate efficacy, safety and tolerability of the Renew® Insert for conservative management of ABL.

DESIGN

Multi-center, prospective, open-label, single-arm cohort.

PATIENTS

Subjects ≥18 years old with ABL severity score ≥12/20, and at least weekly leakage of solid and/or liquid stool.

INTERVENTIONS

12 weeks of continuous Renew insert use.

MAIN OUTCOME MEASURES

Bowel diaries, ABL severity, adverse events, and satisfaction. Percent reduction in leakage frequency and ABL severity were assessed. Sample size calculations estimated 76 subjects would detect a 10% reduction in ABL frequency with 90% power. Paired T-test and Wilcoxon tests were used as appropriate.

RESULTS

This pivotal clinical trial collected data over 24 months on 91 subjects who used approximately 18,779 Renew Inserts. 85 subjects completed at least one week of treatment. Median ABL frequency was reduced by 82% from a median of 0.89 ABL episodes (mean 1.12, +/-0.85) per day at baseline to a median of 0.17 ABL episodes (mean 0.29, +/-0.38) per day at 12 weeks ($p < 0.001$). 78% of subjects had ≥50% reduction in ABL frequency, mean ABL severity scores improved by 32.4% (16.2, +/-2.1 vs. 10.9, +/-4.4 out of 20, $p<0.001$) and 78% of subjects were very or extremely satisfied with the Renew Insert with no serious adverse events related to device use. 97.6% of the reported adverse events were rated as mild; the majority of these events related to mild irritation or the feeling of urge. Pre-treatment and end of treatment anal canal and lower rectal mucosa evaluations (digital rectal examinations and anoscopies) were performed and showed no evidence of irritation of the anal canal or lower rectal mucosa in all 77 subjects evaluated.

CONCLUSIONS

The Renew insert provides a conservative, safe and effective management strategy for individuals with ABL, with high patient satisfaction and low adverse event rates.

US Pivotal Clinical Trial (210CLD) – results submitted for publication

PRINCIPAL INVESTIGATORS:

1. Steve Wexner, MD, PhD Chair, Department of Colorectal Surgery, Cleveland Clinic, Weston, FL USA
2. Emily Lukacz, MD, Director, Female Pelvic Medicine and Reconstructive Surgery; University of California, San Diego, CA USA
3. Mark Segall, MD, Colorectal Surgeon, Los Gatos, CA USA

35 MONTH UK CONSUMER PANEL*

INCLUSION CRITERIA

Community based UK females ≥ 30 years old with daily/weekly ABL and a total Wexner score of > 14, who had no severe or complicating pre-existing medical conditions that could impede usage of Renew Inserts. The Wexner faecal incontinence sums the scores 0 (absent) to 4 (daily) frequency of incontinence to gas, liquid, solid, of need to wear pad, and of lifestyle changes with 0 = full continence and 20 = full incontinence.

ENROLLED

19 subjects consented to participating in continuous use; 11 completed consistent use of Renew Inserts for 35 months.

SATISFACTION

Users consistently reported an extremely high level of satisfaction with Renew Inserts with a 35 month average rating of 4.8 on a 5-point scale, where 5 is extremely satisfied.

OVERALL INSERTION EXPERIENCE

Users consistently rated their overall insertion experience very positively with a 35 month average rating of 9.5 on a 10-point scale, where 10 is straight forward, simple, and comfortable, resulting in an overall very positive experience.

EFFICACY

Among the 11 users who consistently used the Renew Insert during the 35 months, incontinence frequency decreased across all five parameters of the Wexner scale from baseline to post 35 months of use. Users experienced, on average, a 69% decrease in their total Wexner score as compared to baseline. The decrease in the total Wexner score was comprised of an 80% decrease in solid faeces incontinence, an 80% decrease in liquid faeces incontinence, a 50% decrease in gas incontinence, an 83% decrease in the frequency with which consumers used pads or diapers to manage their condition, and a 75% decrease in the extent to which the condition impacted their quality of life.

LABELLING

The existing IFU and FAQs provided sufficient information and were easily understood by users, with 24-month average ratings of 4.9, where 5 is extremely easy [to understand]. Furthermore, most users reported that that they did consult the IFU during the first month of use, but, thereafter, referred back to it only intermittently and primarily only during the first six months of use.

SAFETY EVALUATION

Only six complaints were reported during the 35 month treatment period (three of which were reported by the same user), all of which were attributed to the performance of the Renew Insert and none of which were considered reportable adverse events.

CONCLUSION

After 35 months of continuous use, the analysis of 11 users demonstrated that the Renew Insert was well-liked, having consistently achieved strong satisfaction, likeability, and overall insertion experience ratings. The Renew Insert has been shown to be a safe, simple, comfortable and user-friendly device that can be easily inserted by the user and is effective in reducing the frequency of ABL. The study also showed that the current Instructions for Use (IFU) and Frequently Asked Questions (FAQs) provided sufficient information that was easily understood by users.

* Study MKT-008