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Now available for Urge Incontinence in Europe and Canada

Health Canada (Medical Device Licence #72024) and Intertek ETL Semko (EC Certification Number 41313189) have approved the use of the Eros Therapy in Canada and Europe for treating Urinary Urgency-Frequency and Urge Incontinence (also known as Overactive Bladder). This New Indication for use has been approved in Canada and Europe only.
The following information provides a summary of the Clinical Protocol.

Clinical Data Summary and Analysis

Data were obtained from two clinical research centers in a population of adult women with chronic urinary urgency-frequency and urge incontinence. All patients completed pre-treatment (baseline) and post-treatment 48-hour diaries recording their number of voids, incontinent events, and voided volume. These diaries were evaluated at baseline to determine urinary urge incontinent episodes (greater or equal to 2) and/or voiding frequency (greater than 20). Changes from baseline were noted with a reduction in the number of urge incontinent events by greater than or equal to 50% in the 48-hour diary defined as "improvement," and no recorded urge incontinent events being defined as "cured." The secondary objective was to evaluate the effectiveness of the Eros-CTD to reduce the number of voids in this same group of adult women whose urgency-frequency episodes exceeded 20 times in a 48-hour diary. A reduction of greater than or equal to 50% in the 48-hour diary is defined as "improvement," and fewer than or equal to 20 voids in the 48-hour diary is defined as "cured." Both centers used the same protocol.

The resulting ordinal data were analyzed using the non-parametric Wilcoxin Signed Ranks Test in the SPSS Base 9.0 Statistical Software package. A value of $p < 0.05$ was considered statistically significant. All subjects were evaluated with respect to safety and efficacy.

Safety

Study subjects were instructed to use the device daily at a comfortable vacuum level gradually building up intermittent use to 15 to 20 minutes with one-minute rest periods. None of the women reported any adverse clinical effects including; skin irritation, hematoma, compromise of skin integrity, infection, or allergic response to the materials used.

Efficacy:

Of the total of 25 study subjects, 23 subjects qualified for the study under the primary outcome variable of urge incontinence and 12 subjects met the secondary inclusion criterion for voiding frequency.
Outcome evaluations were conducted at 6 to 16 weeks post device use because the device had demonstrated such significant benefits. Of 23 subjects with urge incontinence, 10 were cured and 8 were improved ($p<0.01$). For the remaining 5 subjects, 2 subjects experienced a reduction of incontinent episodes and three experienced no benefit. Of 12 subjects with

voiding symptoms, 8 were cured and 1 was improved ($p<0.01$). For the remaining 3 subjects, 2 experienced a reduction of voiding frequency and 1 had no benefit.

We analyzed the response to treatment reported by the women with chronic urinary urgency-frequency and urge incontinence. Each woman served as her own control. Analysis by Wilcoxon Signed Ranks Test for paired observations achieved statistical significance ($p< 0.05$) as shown in tables 1 and 2.

Table 1. Women with symptoms of urinary urge incontinence

		Cured	Improved	Efficacy
Subjects		10 (43%)	8 (35%)	78% (18/23), $p < .01$
n=		23	23	23

Table 2. Women with symptoms of urinary urgency-frequency

		Cured	Improved	Efficacy
Subjects		8 (67%)	1 (8%)	75% (9/12), $p < .01$
n=		12	12	12

Clinical Protocol Summary

The Effect of Eros-CTD™ Device on Urinary Urgency-Frequency and Urge Incontinence in Neurologically Intact Females, Steven Wilson, L. Dean Knoll. Van Buren, AR and Nashville, TN

Introduction:

The Eros-Clitoral Therapy Device (CTD)™ (UroMetrics, Inc. St. Paul, MN, USA) is cleared-to-market for treatment of symptoms of Female Sexual Dysfunction (FSD). This clitoral engorgement device has been reported to greatly improve genital sensation, vaginal lubrication, orgasm and overall sexual satisfaction. Additionally, eleven subjects in these studies self-reported a secondary clinical benefit of the therapy. These subjects spontaneously reported that they experienced complete resolution of symptoms of urinary urgency-frequency and urge incontinence following twelve weeks of use of the Eros-CTD. A two-center study, Wilson Urology, Van Buren, AR and The Center for Urological Research and Development, Nashville, TN, was conducted to determine the efficacy of this device for treatment of urinary urgency-frequency and urge incontinence symptoms.

Study Objectives:

The primary objective of this study was to evaluate the effectiveness of the Eros-CTD (Urge Incontinence Indication), to reduce the number of urge incontinent events by greater than or equal to 50% in a population of adult women with chronic urinary urgency-frequency and urge incontinence. The secondary objective was to evaluate the effectiveness of the Eros Device to reduce the number of voids by greater than or equal to 50% or to reduce the number of voids per day ($\leq$10) in this same group of adult women.

Methods:

Following IRB approval and meeting enrollment inclusion/ exclusion criteria for the study, twenty-five women with chronic urinary urgency-frequency and/ or urge incontinence from two different centers were accepted into the study. Study subjects were required to have a primary diagnosis of urinary urgency-frequency or urge incontinence, negative urine cytology, an average functional bladder capacity of less than 250cc/day, a negative UTI

test, and a 2 week wash out prior to study admission if on pharmaceuticals. Each subject completed a 48 hour baseline diary and was evaluated for urinary urge incontinent episodes (greater or equal to 2) and voiding frequency (greater than 20). Subjects with implantable sacral nerve stimulators or related incontinence surgeries were not allowed to participate in the study. Subjects who qualified for the study were asked to sign informed consent and were instructed on proper daily therapeutic device use.

Patients were instructed to read all of the sections of the instruction manual including the risk section. Study subjects were instructed to use the device daily at a comfortable vacuum level gradually building up intermittent use to 15 to 20 minutes with 1 minute rest periods. A two-day diary of fluid intake, voiding frequency and volume, incontinent episodes and use compliance was completed by each subject each week and turned in to the clinical study coordinator weekly for the first 6 weeks, and every other week thereafter until week 16. A pelvic exam and voiding volume measurement (functional bladder capacity) were completed in office.

Subjects were categorized as cured of urge incontinence if they experienced no incontinent episodes in their most recent 2 day diary, improved if their number of incontinent episodes decreased by 50% or greater, and no effect if their number of incontinent episodes failed to decrease by 50%. Subjects were categorized as cured of voiding frequency symptoms if they voided 10 or fewer times per day in their most recent 2 day diary, improved if their voiding frequency decreased by 50% or greater and no benefit if their voiding frequency failed to decrease 50%.