ValUE

Screening Log

Version 10/27/08 (A)

Site: ____ ____ ____ **Start Date: ___ ___/___ ___/___ ___ ___ ___**

	ValUE			
Seq. #	**Consented?** Code: 1 (Yes) and Study ID 2 (No) 3 (In Screening – temp code/ must finalize)	**Excluded?** (Refer to back for Exc. Codes) Code: -1 (N/A, Patient eligible) -3 (Patient still in screening)	**Repeat Screen?** Code: 1 (Yes) 2 (No)	**Entered?** (DM use only)

ValUE Inclusion, Exclusion & "Other" Codes

Code	Inclusion Description	Code	Exclusion Description
I1	Signed consent form	**E1**	Age <21 years
I2	Female	**E2**	Pregnant or has not completed child bearing.
I3	Available for 12 months of follow-up and able to complete study assessments as per clinician judgment	**E3**	< 12 months post-partum
I4	Negative urine dipstick (negative result = trace or less for leukocytes & nitrites) or negative UA or negative culture	**E4**	Active malignancy of cervix, uterus, fallopian tube(s) or ovary > Stage I, or bladder of any Stage
		E5	Current catheter use
		E6	Participation in another treatment intervention trial that might influence results of this study.
		VE2	Currently undergoing or has had recommended treatment of apical or anterior prolapse
		VE3	No anterior or apical prolapse ≥ +1 on standing straining prolapse exam
		VE7	History of pelvic radiation therapy
VI2a	Predominant SUI as evidenced by self-reported stress-type UI symptoms, of duration >3 months	**VE8**	Previous incontinence surgery
VI2b	Predominant SUI as evidenced by MESA stress symptom score (% of total possible stress score) greater than MESA urge symptom score (% of total possible urge score)	**VE10**	Neurological disease known to affect bladder storage (e.g. MS, Parkinsonism, CVA)
VI3	Observation of leakage by provocative stress test at any volume	**VE11**	Previous (i.e. repaired) or current urethral diverticulum
VI4	Eligible for randomization to either treatment group	**VE12**	Prior augmentation cystoplasty or artificial sphincter
VI5	Eligible for SUI surgery	**VE13**	Implanted nerve stimulators for urinary symptoms or previous botox bladder injections.
VI6	Desires non-conservative therapy for SUI	**VE14**	Any pelvic surgery within the last 3 months
VI7	PVR <150ml by any method. (May repeat once if initial measure is abnormal)	**VE15**	Previous placement of synthetic mesh on a vaginal approach in the anterior compartment
VI9	Available to initiate SUI treatment within 6 weeks of randomization	**VE17**	A urodynamic result reviewed by the investigator in the preceding 12 months or any recollection by the investigator of urodynamic results on that subject.
Other Codes & Descriptions			
99	Other (brief explanation of "Other" required)	**81**	Insurance reasons
		82	No site staff certified in Spanish and/or other non-English language
78	Refused study procedures (i.e. too invasive, too much time)		
79	Prior to DCC-confirmed site certification		
80	Refused randomization	**85**	Not approved to start study (e.g. IRB delay)