

SECTION A: ID ASSIGNMENT AND GENERAL INFORMATION

- A1.** Study ID#:
- A2.** Visit # Baseline VBAS
- A3.** Date Form Completed: ___/___/___
Month Day Year
- A4.** Study Staff Initials: _____
- A5.** Is this a repeat abstraction due to expired measures? Yes..... 1 No..... 2

SECTION B: INCLUSION CRITERIA

	YES	NO
B1. Has the patient given informed consent to participate? B1a. Date Consent Signed: ___/___/___ Month Day Year	1	2 ↓ DO NOT PROCEED
B2. Is the patient female?	1	2
B3. Self-reported stress-type urinary incontinence symptoms ≥ 3 months?	1	2
B4a. Document MESA Stress Index ___ %		
B4b. Document MESA Urge Index ___ %		
B4c. Do the MESA index scores indicate predominant stress incontinence?	1	2
B5. Leakage by provocative stress test at any volume?	1	2
B6. Eligible for randomization to either treatment group?	1	2
B7. Eligible for stress urinary incontinence surgery?	1	2
B8. Desires non-conservative therapy for stress urinary incontinence?	1	2
B9. PVR < 150 mL (by any method)?	1	2
B10. Negative urine dipstick (result = trace or less for leukocytes or nitrites) <u>or</u> negative UA <u>or</u> negative culture within the past 3 months? B10a. Date of Test: ___/___/___ Month Day Year	1	2
B11. Available to initiate SUI treatment within 6 weeks of randomization?	1	2
B12. Available for twelve months of follow-up?	1	2
B13. Able to complete study assessments per clinician judgment?	1	2

SECTION C: EXCLUSION CRITERIA

	YES	NO
C1. Patient's date of birth: _____ / _____ / _____ Month Day Year		
C1a. Is patient < 21 years of age?	1	2
C2. Currently undergoing or recommended to undergo treatment of apical or anterior prolapse?	1	2
C3. Apical or anterior prolapse \geq +1 on standing/straining exam?	1	2
C4. Currently pregnant?	1	2
C5. Has not completed child bearing?	1	2
C6. Less than 12 months postpartum?	1	2
C7. Active malignancy of cervix, uterus, fallopian tube(s), or ovary > Stage 1?	1	2
C8. Active malignancy of the bladder at any stage?	1	2
C9. History of pelvic radiation therapy?	1	2
C10. Previous incontinence surgery?	1	2
C11. Current catheter use?	1	2
C12. Neurological disease known to affect bladder storage (e.g. MS, Parkinsonism, CVA)?	1	2
C13. Previous (i.e. repaired) or current urethral diverticulum?	1	2
C14. Prior augmentation cystoplasty?	1	2
C15. Prior artificial sphincter?	1	2
C16. Implanted nerve stimulators for urinary symptoms?	1	2
C17. Previous botox bladder injections?	1	2
C18. Any pelvic surgery within the last 3 months?	1	2
C19. Previous placement of synthetic mesh on a vaginal approach in the anterior compartment?	1	2
C20. Participation in another trial that may influence the results of this study?	1 ↓	2 → C21
C20a. Has the UITN Eligibility Committee approved her enrollment?	1	2
C21. UDS data reviewed by Investigator in the last 12 months or any recollection by Investigator of UDS results for subject?	1	2

SECTION D: ELIGIBILITY SUMMARY

D1. Are any of the above data > 12 months old?

Yes 1 → **INELIGIBLE; MEASURE(S) MUST BE REPEATED PRIOR TO RANDOMIZATION**

No 2

D2. Does the patient meet all eligibility criteria as documented on this form?

Yes 1

No 2 → **INELIGIBLE; DO NOT PROCEED WITH RANDOMIZATION**

SECTION E: INVESTIGATOR SIGNATURE

My signature confirms that I have reviewed all of the information on this Form and I am confirming its accuracy.

Investigator's Signature: _____ Initials: _____ Date: _____ / _____ / _____
Month Day Year

