

F524: Post-UDS Surgeon Diagnosis and Treatment, version 09/29/08 (A)

SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY

A1. Study ID#: A2. Visit # UDS VUDS

A3. Date Form Completed: ___/___/___
Month Day Year A4. Initials of Certified Surgeon Investigator: _____

NOTE: TO BE COMPLETED AFTER FORM 505 (Urodynamic Data) AND WITHOUT REVIEWING FORM 514 (Baseline Surgeon Diagnosis and Treatment)

SECTION B: CLINICAL DIAGNOSIS

Based on your clinical evaluation which now includes the additional urodynamic diagnostic testing, circle "Yes" or "No" for whether you think the patient has this clinical diagnosis.

For every "Yes" or "No" response, please rate how confident (sure) you are about the presence or absence of this clinical diagnosis.

| | Yes | No | Not Very Confident (< 50%) | Somewhat Confident (50-74%) | Moderately Confident (75-84%) | Very Confident (85-94%) | Extremely Confident (≥ 95%) |
|---------------------------------|-----|----|----------------------------|-----------------------------|-------------------------------|-------------------------|-----------------------------|
| B1. Stress urinary incontinence | 1 | 2 | 1 | 2 | 3 | 4 | 5 |

| SUI | Frequency | Percent | Cum Freq | Cum Percent |
|-------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 292 | 99.32 | 292 | 99.32 |
| 2:No | 2 | 0.68 | 294 | 100.00 |

Frequency Missing = 336

| SUI_CONF | Frequency | Percent | Cum Freq | Cum Percent |
|----------------------------------|-----------|---------|----------|-------------|
| . | 337 | . | . | . |
| 1: Not Very Confident (< 50%) | 1 | 0.34 | 1 | 0.34 |
| 2: Somewhat Confident (50-74%) | 2 | 0.68 | 3 | 1.02 |
| 3: Moderately Confident (75-84%) | 6 | 2.05 | 9 | 3.07 |
| 4: Very Confident (85-94%) | 87 | 29.69 | 96 | 32.76 |
| 5: Extremely Confident (>95%) | 197 | 67.24 | 293 | 100.00 |

Frequency Missing = 337

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| B2. OAB with incontinence (or OAB-wet, Urge Incontinence) | 1 | 2 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|---|

| OAB_INC | Frequency | Percent | Cum Freq | Cum Percent |
|---------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 74 | 25.17 | 74 | 25.17 |
| 2:No | 220 | 74.83 | 294 | 100.00 |

Frequency Missing = 336

| OAB_INC_CONF | Frequency | Percent | Cum Freq | Cum Percent |
|----------------------------------|-----------|---------|----------|-------------|
| . | 337 | . | . | . |
| 1: Not Very Confident (< 50%) | 2 | 0.68 | 2 | 0.68 |
| 2: Somewhat Confident (50-74%) | 20 | 6.83 | 22 | 7.51 |
| 3: Moderately Confident (75-84%) | 85 | 29.01 | 107 | 36.52 |
| 4: Very Confident (85-94%) | 127 | 43.34 | 234 | 79.86 |
| 5: Extremely Confident (>95%) | 59 | 20.14 | 293 | 100.00 |

Frequency Missing = 337

| | | | | | | | |
|--|---|---|---|---|---|---|---|
| B3. OAB without incontinence (or OAB-dry, Urgency/ Frequency syndrome) | 1 | 2 | 1 | 2 | 3 | 4 | 5 |
|--|---|---|---|---|---|---|---|

| OAB | Frequency | Percent | Cum Freq | Cum Percent |
|-------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 61 | 20.75 | 61 | 20.75 |
| 2:No | 233 | 79.25 | 294 | 100.00 |

Frequency Missing = 336

| OAB_CONF | Frequency | Percent | Cum Freq | Cum Percent |
|----------------------------------|-----------|---------|----------|-------------|
| . | 337 | . | . | . |
| 2: Somewhat Confident (50-74%) | 23 | 7.85 | 23 | 7.85 |
| 3: Moderately Confident (75-84%) | 94 | 32.08 | 117 | 39.93 |
| 4: Very Confident (85-94%) | 130 | 44.37 | 247 | 84.30 |
| 5: Extremely Confident (>95%) | 46 | 15.70 | 293 | 100.00 |

Frequency Missing = 337

| | | | | | | | |
|--|---|---|---|---|---|---|---|
| B4. Voiding phase dysfunction (Emptying Problems) | 1 | 2 | 1 | 2 | 3 | 4 | 5 |
|--|---|---|---|---|---|---|---|

| VPD | Frequency | Percent | Cum Freq | Cum Percent |
|-------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 35 | 11.90 | 35 | 11.90 |
| 2:No | 259 | 88.10 | 294 | 100.00 |

Frequency Missing = 336

| VPD_CONF | Frequency | Percent | Cum Freq | Cum Percent |
|----------------------------------|-----------|---------|----------|-------------|
| . | 338 | . | . | . |
| 1: Not Very Confident (< 50%) | 1 | 0.34 | 1 | 0.34 |
| 2: Somewhat Confident (50-74%) | 13 | 4.45 | 14 | 4.79 |
| 3: Moderately Confident (75-84%) | 66 | 22.60 | 80 | 27.40 |
| 4: Very Confident (85-94%) | 131 | 44.86 | 211 | 72.26 |
| 5: Extremely Confident (>95%) | 81 | 27.74 | 292 | 100.00 |

Frequency Missing = 338

| | | | | | | | |
|--|---|---|---|---|---|---|---|
| B5. Suspected intrinsic sphincter deficiency (ISD) | 1 | 2 | 1 | 2 | 3 | 4 | 5 |
|--|---|---|---|---|---|---|---|

| ISD | Frequency | Percent | Cum Freq | Cum Percent |
|-------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 37 | 12.59 | 37 | 12.59 |
| 2:No | 257 | 87.41 | 294 | 100.00 |

Frequency Missing = 336

| ISD_CONF | Frequency | Percent | Cum Freq | Cum Percent |
|----------------------------------|-----------|---------|----------|-------------|
| . | 337 | . | . | . |
| 1: Not Very Confident (< 50%) | 2 | 0.68 | 2 | 0.68 |
| 2: Somewhat Confident (50-74%) | 14 | 4.78 | 16 | 5.46 |
| 3: Moderately Confident (75-84%) | 65 | 22.18 | 81 | 27.65 |
| 4: Very Confident (85-94%) | 137 | 46.76 | 218 | 74.40 |
| 5: Extremely Confident (>95%) | 75 | 25.60 | 293 | 100.00 |

Frequency Missing = 337

SECTION C: TREATMENT PLAN

C1. Do you still intend to proceed with surgery for this patient? Yes 1
No..... 2 → SKIP TO C4

| PROCEED_SURG | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 290 | 98.64 | 290 | 98.64 |
| 2:No | 4 | 1.36 | 294 | 100.00 |

Frequency Missing = 336

C2.Which SUI surgery is planned for this patient? Midurethral Sling 1 → SKIP TO C2b
Traditional Sling..... 2 → SKIP TO C2c
Retropubic Urethropexy 3 → SKIP TO C3
Urethral Bulking Injection..... 4 → SKIP TO C2d
Other Surgical Procedure 5 ↓

| SUI_SURG | Frequency | Percent | Cum Freq | Cum Percent |
|-------------------------------|-----------|---------|----------|-------------|
| . | 341 | . | . | . |
| 1: Midurethral Sling | 277 | 95.85 | 277 | 95.85 |
| 2: Traditional Sling | 9 | 3.11 | 286 | 98.96 |
| 4: Urethral Bulking Injection | 3 | 1.04 | 289 | 100.00 |

Frequency Missing = 341

C2a. If Other, specify: _____ → SKIP TO C3

| SUI_SURG_SPE | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| . | 630 | 100.00 | 630 | 100.00 |

C2b. What kind of midurethral sling? Retropubic 1
 Transobturator 2
 Minisling 3

| MID_SLING | Frequency | Percent | Cum Freq | Cum Percent |
|-------------------|-----------|---------|----------|-------------|
| . | 353 | . | . | . |
| 1: Retropubic | 192 | 69.31 | 192 | 69.31 |
| 2: Transobturator | 78 | 28.16 | 270 | 97.47 |
| 3: Minisling | 7 | 2.53 | 277 | 100.00 |

Frequency Missing = 353

C2c. What kind of traditional sling? Autologous 1
 Allogenic 2
 Xenograft 3
 Synthetic 4

SKIP TO C3

| TRAD_SLING | Frequency | Percent | Cum Freq | Cum Percent |
|---------------|-----------|---------|----------|-------------|
| . | 621 | . | . | . |
| 1: Autologous | 9 | 100.00 | 9 | 100.00 |

Frequency Missing = 621

C2d. What kind of urethral bulking injection? Collagen 1
 Non-collagen material 2 ↓

C2di. Specify non-collagen material: _____

C3. Any planned modifications to your conventional performance of this surgery? Yes..... 1
 No..... 2 → SKIP TO C4

| SUI_SURG_MOD_cat | Frequency | Percent | Cum Freq | Cum Percent |
|------------------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 24 | 8.16 | 24 | 8.16 |
| 2:No/Missing | 270 | 91.84 | 294 | 100.00 |

Frequency Missing = 336

| | Yes | No |
|-----------------------|-----|----|
| C3a. More Obstructive | 1 | 2 |
| b. Less Obstructive | 1 | 2 |

| MOD_LESS_OBS_cat | Frequency | Percent | Cum Freq | Cum Percent |
|------------------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 21 | 7.14 | 21 | 7.14 |
| 2:No/Missing | 273 | 92.86 | 294 | 100.00 |

Frequency Missing = 336

C3c. Other: 1 ↓ 2 ➔ **SKIP TO C4**

C3ci. If Other, Specify: _____

C4. Is any other additional therapy included in the treatment plan for this patient? Yes..... 1
 No..... 2 ➔ **SKIP TO C5**

| THERAPY | Frequency | Percent | Cum Freq | Cum Percent |
|---------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 40 | 13.61 | 40 | 13.61 |
| 2:No | 254 | 86.39 | 294 | 100.00 |

Frequency Missing = 336

Specify additional therapy. Circle "Yes" or "No" for each.

| | Yes | No |
|---------------|-----|----|
| C4a. PF Rehab | 1 | 2 |

| THERAPY_PF | Frequency | Percent | Cum Freq | Cum Percent |
|------------|-----------|---------|----------|-------------|
| . | 591 | . | . | . |
| 1:Yes | 19 | 48.72 | 19 | 48.72 |
| 2:No | 20 | 51.28 | 39 | 100.00 |

Frequency Missing = 591

b. Pharmacotherapy

1

2

| THERAPY_PHAR_cat | Frequency | Percent | Cum Freq | Cum Percent |
|------------------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 25 | 8.50 | 25 | 8.50 |
| 2:No/Missing | 269 | 91.50 | 294 | 100.00 |

Frequency Missing = 336

c. Other

1 ↓

2 → SKIP TO C5

C4ci. If Other, Specify: _____

C5. Overall, how confident are you that you have made the best treatment plan for this subject? Please circle one.

NOTE: This question is not about the efficacy of the treatment itself.

| Not Very Confident (< 50%) | Somewhat Confident (50-74%) | Moderately Confident (75-84%) | Very Confident (85-94%) | Extremely Confident (≥ 95%) |
|-------------------------------|--------------------------------|----------------------------------|----------------------------|--------------------------------|
| 1 | 2 | 3 | 4 | 5 |

| TR_PLAN_CONF | Frequency | Percent | Cum Freq | Cum Percent |
|----------------------------------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 2: Somewhat Confident (50-74%) | 3 | 1.02 | 3 | 1.02 |
| 3: Moderately Confident (75-84%) | 19 | 6.46 | 22 | 7.48 |
| 4: Very Confident (85-94%) | 174 | 59.18 | 196 | 66.67 |
| 5: Extremely Confident (>95%) | 98 | 33.33 | 294 | 100.00 |

Frequency Missing = 336

C6. To what degree did the patient participate in the decision about planned SUI surgery? Please circle one.

| Minimally Involved | Somewhat Involved | Moderately Involved | Very Involved | Extremely Involved |
|--------------------|-------------------|---------------------|---------------|--------------------|
| 1 | 2 | 3 | 4 | 5 |

| DECISION | Frequency | Percent | Cum Freq | Cum Percent |
|------------------------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 2: Somewhat Involved | 1 | 0.34 | 1 | 0.34 |
| 3: Moderately Involved | 20 | 6.80 | 21 | 7.14 |
| 4: Very Involved | 156 | 53.06 | 177 | 60.20 |
| 5: Extremely Involved | 117 | 39.80 | 294 | 100.00 |

Frequency Missing = 336

C7. What do you expect to be the most likely method of bladder emptying at discharge?

Spontaneous voiding 1

Any catheter-assisted bladder drainage 2

| DISCHRG_PLAN | Frequency | Percent | Cum Freq | Cum Percent |
|----------------------------------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1: Spontaneous voiding | 237 | 80.61 | 237 | 80.61 |
| 2: Any catheter-assisted bladder | 57 | 19.39 | 294 | 100.00 |

Frequency Missing = 336

SECTION D: COUNSELING AND POTENTIAL COMPLICATIONS

Circle “Yes” or “No” for the potential complications listed below that were discussed with this patient. This includes any additional discussion which may have happened after UDS testing. For any “Yes” responses, indicate the level of risk for this complication for this patient compared to the average or typical patient undergoing this SUI procedure. When interpreting the term “typical,” please consider the “typical” patient to be a typical patient in your practice who would meet eligibility for this study.

D1. Risk of urgency, frequency Yes 1 No 2 ➔ SKIP TO D2

| RISK_URGE_FR | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 274 | 93.20 | 274 | 93.20 |
| 2:No | 20 | 6.80 | 294 | 100.00 |

Frequency Missing = 336

D1a. Risk for this patient:

| Low Risk | Typical | | | | | High Risk | | | | |
|----------|---------|---|---|---|---|-----------|---|---|----|--|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |

| PAT_URGE_RSK_cat | Frequency | Percent | Cum Freq | Cum Percent |
|-----------------------|-----------|---------|----------|-------------|
| . | 356 | . | . | . |
| 1:Low Risk/2: | 28 | 10.22 | 28 | 10.22 |
| 3: | 37 | 13.50 | 65 | 23.72 |
| 4: | 136 | 49.64 | 201 | 73.36 |
| 5:Typical | 22 | 8.03 | 223 | 81.39 |
| 6:/7:/8:/10:High Risk | 26 | 9.49 | 249 | 90.88 |
| 6 | 25 | 9.12 | 274 | 100.00 |

Frequency Missing = 356

D2. Risk of urge UI

Yes 1 No 2 ➔ **SKIP TO D3**

| RISK_URGE_UI | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 262 | 89.12 | 262 | 89.12 |
| 2:No | 32 | 10.88 | 294 | 100.00 |

Frequency Missing = 336

D2a. Specify Type of Urge UI: Persistent 1 De Novo..... 2

| URGE_UI_TYPE | Frequency | Percent | Cum Freq | Cum Percent |
|---------------|-----------|---------|----------|-------------|
| . | 371 | . | . | . |
| 1: Persistent | 115 | 44.40 | 115 | 44.40 |
| 2: De Novo | 144 | 55.60 | 259 | 100.00 |

Frequency Missing = 371

D2b. Risk for this patient:

| Low Risk | | Typical | | | | High Risk | | | |
|----------|---|---------|---|---|---|-----------|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

| PAT_UI_RSK_cat | Frequency | Percent | Cum Freq | Cum Percent |
|-----------------------|-----------|---------|----------|-------------|
| . | 368 | . | . | . |
| 1:Low Risk/2: | 29 | 11.07 | 29 | 11.07 |
| 3: | 40 | 15.27 | 69 | 26.34 |
| 4: | 119 | 45.42 | 188 | 71.76 |
| 5:Typical | 32 | 12.21 | 220 | 83.97 |
| 6:/7:/8:/10:High Risk | 21 | 8.02 | 241 | 91.98 |
| 6 | 21 | 8.02 | 262 | 100.00 |

Frequency Missing = 368

D3. Risk of urinary retention from anti-incontinence surgery

Yes 1 No 2 ➔ **SKIP TO D4**

D3a. Risk for this patient:

| Low Risk | | Typical | | | | High Risk | | | |
|----------|---|---------|---|---|---|-----------|---|---|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

| PAT_RET_RSK_cat | Frequency | Percent | Cum Freq | Cum Percent |
|-----------------|-----------|---------|----------|-------------|
| . | 350 | . | . | . |
| 1:Low Risk/2: | 47 | 16.79 | 47 | 16.79 |
| 3:/4: | 44 | 15.71 | 91 | 32.50 |
| 5:Typical | 146 | 52.14 | 237 | 84.64 |
| 6:/7:/8:/9:/10: | 43 | 15.36 | 280 | 100.00 |

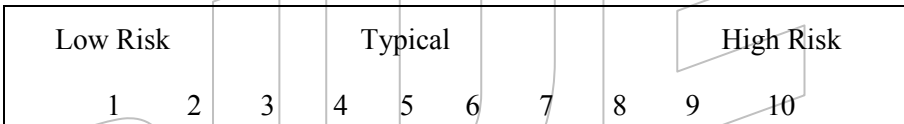
Frequency Missing = 350

D4. Risk of failure to treat SUI Yes 1 No 2 ➔ **SKIP TO SECTION E**

| RISK_FAIL | Frequency | Percent | Cum Freq | Cum Percent |
|-----------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 278 | 94.56 | 278 | 94.56 |
| 2:No | 16 | 5.44 | 294 | 100.00 |

Frequency Missing = 336

D4a. Risk for this patient:



| PAT_FAIL_RSK_cat | Frequency | Percent | Cum Freq | Cum Percent |
|-----------------------|-----------|---------|----------|-------------|
| . | 352 | . | . | . |
| 1:Low Risk/2: | 42 | 15.11 | 42 | 15.11 |
| 3: | 28 | 10.07 | 70 | 25.18 |
| 4: | 24 | 8.63 | 94 | 33.81 |
| 5:Typical | 157 | 56.47 | 251 | 90.29 |
| 6:/7:/8:/10:High Risk | 27 | 9.71 | 278 | 100.00 |

Frequency Missing = 352

SECTION E: SURGEON'S SIGNATURE

Surgeon's Signature: _____ Date: ____/____/____
Month Day Year

| SURG_SIGN | Frequency | Percent | Cum Freq | Cum Percent |
|-----------|-----------|---------|----------|-------------|
| . | 336 | . | . | . |
| 1:Yes | 294 | 100.00 | 294 | 100.00 |

Frequency Missing = 336

| Analysis Variable : rando_dt_SURG_SIGN_D | | | | | | | | |
|--|--------|-------|------|---------|----------------|--------|----------------|---------|
| N | N Miss | Mean | SD | Minimum | Lower Quartile | Median | Upper Quartile | Maximum |
| 294 | 336 | -17.5 | 26.3 | -299.0 | -24.0 | -11.0 | -4.0 | 0.0 |

