

**Section A: General Study Information for Office Use Only:**

A1. Study ID#:  A2. Visit # Surgery.....TSRG  
 A3. Date Form Completed: \_\_\_/\_\_\_/\_\_\_  
 Month Day Year A4. Initials of Person Completing Section B: \_\_\_\_\_  
 (Certified Surgeon of Record)

**SECTION B: ADVERSE EVENTS AND COMPLICATIONS – POST OPERATIVE**

B1. Did the patient receive a **red blood cell transfusion** in the post-operative period?

Yes..... 1↓ No..... 2 → **SKIP TO B2**

**Because the frequency of at least one category is very low, the variable was not included in the dataset**

*\*REMINDER: COMPLETE FORM 391 AS REQUIRED\**

B1a. Number of **autologous** units: \_\_\_\_\_ units

**Because the frequency of at least one category is very low, the variable was not included in the dataset**

B1b. Number of **non-autologous** units: \_\_\_\_\_ units

**Because the frequency of at least one category is very low, the variable was not included in the dataset**

B2. Did any adverse events or complications occur in the post-operative period? **REVIEW BOX AT BOTTOM OF PAGE**

Yes..... 1↓ No..... 2 → **SKIP TO SECTION C**

| AE_POSTOP | Frequency | Percent | Cum Freq | Cum Percent |
|-----------|-----------|---------|----------|-------------|
| 1         | 10        | 1.68    | 10       | 1.68        |
| 2         | 587       | 98.32   | 597      | 100.00      |

|    | Event Number<br>(Refer to Pt AE Log) | Event Code<br>(Refer to Box Below) | If Event Code = 99, Specify |
|----|--------------------------------------|------------------------------------|-----------------------------|
| a. | _____                                | _____ →                            |                             |
| b. | _____                                | _____ →                            |                             |
| c. | _____                                | _____ →                            |                             |
| d. | _____                                | _____ →                            |                             |
| e. | _____                                | _____ →                            |                             |
| f. | _____                                | _____ →                            |                             |

|    |       |         |  |
|----|-------|---------|--|
| g. | _____ | _____ → |  |
|----|-------|---------|--|

**\*REMINDER: COMPLETE SEPARATE FORM F391 FOR EACH ADVERSE EVENT OR COMPLICATION LISTED\***

| <b>EVENT CODES REFERENCE FOR B2</b> |                                 |   |                              |
|-------------------------------------|---------------------------------|---|------------------------------|
| 01 = Bladder Perforation            | 09 = CVA                        | 17 = Mesh Complication: Exposure                        | 23 = Recurrent UTI           |
| 02 = Urethral Perforation           | 10 = Death                      | 18 = Surgical Site Infection:<br>Superficial Incisional | 24 = Fistula: Vesicovaginal  |
| 03 = Acute Renal Failure            | 11 = Intraoperative Bleeding    | 19 = Surgical Site Infection: Deep<br>Incisional        | 25 = Fistula: Urethrovaginal |
| 04 = Anesthetic Complication        | 12 = Postoperative Bleeding     | 20 = Surgical Site Infection:<br>Organ/Space            | 26 = Fistula: Enterovesical  |
| 05 = Device Malfunction             | 13 = Bowel Injury               | 21 = Culture-Proven UTI                                 | 27 = Fistula: Rectovaginal   |
| 06 = DVT                            | 14 = Rectal Injury              | 22 = Empiric UTI  | 28 = Neurologic Symptoms     |
| 07 = Pulmonary Embolus              | 15 = Vascular Injury            |   | 99 = Other                   |
| 08 = MI                             | 16 = Mesh Complication: Erosion |   |                              |

TOMMUS

**SECTION C: RETROGRADE FILL VOIDING TRIAL**

SECTION C MAY BE COMPLETED BY A TOMUS CERTIFIED DATA COLLECTOR.

C1. Was a voiding trial completed prior to discharge?

Yes..... 1 No .....2

| RETRO_VT | Frequency | Percent | Cum Freq | Cum Percent |
|----------|-----------|---------|----------|-------------|
| 1        | 582       | 97.49   | 582      | 97.49       |
| 2        | 15        | 2.51    | 597      | 100.00      |

C1a. What was the date of the last voiding trial? Date of surgery ..... 1 → **SKIP TO C2**

Later than the date of surgery ..... 2

Trial not done prior to discharge ..... 3 → **SKIP TO C1aii**

| LAST_VT | Frequency | Percent | Cum Freq | Cum Percent |
|---------|-----------|---------|----------|-------------|
| 1       | 395       | 66.16   | 395      | 66.16       |
| 2       | 190       | 31.83   | 585      | 97.99       |
| 3       | 12        | 2.01    | 597      | 100.00      |

C1ai. Specify date voiding trial performed:

Month / Day / Year

| VT_Days | Frequency | Percent | Cum Freq | Cum Percent |
|---------|-----------|---------|----------|-------------|
| .       | 407       | .       | .        | .           |
| 1       | 172       | 90.53   | 172      | 90.53       |
| 2       | 13        | 6.84    | 185      | 97.37       |
| 3       | 4         | 2.11    | 189      | 99.47       |
| 4       | 1         | 0.53    | 190      | 100.00      |

Frequency Missing = 407

C1aii. Specify reason(s) the trial was not performed or performed later than the date of surgery:

Circle yes or no for all types listed:

|  | YES       | NO      |          |             |         |          |             |    |     |       |     |       |   |     |       |     |       |   |     |       |     |        |
|--|-----------|---------|----------|-------------|---------|----------|-------------|----|-----|-------|-----|-------|---|-----|-------|-----|-------|---|-----|-------|-----|--------|
| a. Concurrent surgery  | 1         | 2       |          |             |         |          |             |    |     |       |     |       |   |     |       |     |       |   |     |       |     |        |
| <table border="1"> <thead> <tr> <th>CON_SURG</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>-2</td> <td>395</td> <td>66.16</td> <td>395</td> <td>66.16</td> </tr> <tr> <td>1</td> <td>118</td> <td>19.77</td> <td>513</td> <td>85.93</td> </tr> <tr> <td>2</td> <td>84</td> <td>14.07</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table> |           |         | CON_SURG | Frequency   | Percent | Cum Freq | Cum Percent | -2 | 395 | 66.16 | 395 | 66.16 | 1 | 118 | 19.77 | 513 | 85.93 | 2 | 84  | 14.07 | 597 | 100.00 |
| CON_SURG   | Frequency | Percent | Cum Freq | Cum Percent |         |          |             |    |     |       |     |       |   |     |       |     |       |   |     |       |     |        |
| -2   | 395       | 66.16   | 395      | 66.16       |         |          |             |    |     |       |     |       |   |     |       |     |       |   |     |       |     |        |
| 1  | 118       | 19.77   | 513      | 85.93       |         |          |             |    |     |       |     |       |   |     |       |     |       |   |     |       |     |        |
| 2  | 84        | 14.07   | 597      | 100.00      |         |          |             |    |     |       |     |       |   |     |       |     |       |   |     |       |     |        |
| b. Bladder perforation   | 1         | 2       |          |             |         |          |             |    |     |       |     |       |   |     |       |     |       |   |     |       |     |        |
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| BLAD_PER   | Frequency | Percent | Cum Freq | Cum Percent |         |          |             |    |     |       |     |       |   |     |       |     |       |   |     |       |     |        |
| -2   | 395       | 66.16   | 395      | 66.16       |         |          |             |    |     |       |     |       |   |     |       |     |       |   |     |       |     |        |
| 1  | 11        | 1.84    | 406      | 68.01       |         |          |             |    |     |       |     |       |   |     |       |     |       |   |     |       |     |        |
| 2  | 191       | 31.99   | 597      | 100.00      |         |          |             |    |     |       |     |       |   |     |       |     |       |   |     |       |     |        |
| c. Vaginal pack  | 1         | 2       |          |             |         |          |             |    |     |       |     |       |   |     |       |     |       |   |     |       |     |        |

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|--|----------------------|---------|----------|-------------|------------|-----------|---------|----------|-------------|----|-----|-------|-----|-------|---|----|-------|-----|-------|---|-----|-------|-----|--------|
| VAG_PACK   | Frequency            | Percent | Cum Freq | Cum Percent |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| -2   | 395                  | 66.16   | 395      | 66.16       |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| 1  | 82                   | 13.74   | 477      | 79.90       |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| 2  | 120                  | 20.10   | 597      | 100.00      |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| d.   | Regional anesthesia  | 1       | 2        |             |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
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| REG_ANESTH   | Frequency            | Percent | Cum Freq | Cum Percent |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| -2   | 395                  | 66.16   | 395      | 66.16       |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| 1  | 2                    | 0.34    | 397      | 66.50       |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| 2  | 200                  | 33.50   | 597      | 100.00      |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| e.   | Over sedation        | 1       | 2        |             |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
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| OVER_SED   | Frequency            | Percent | Cum Freq | Cum Percent |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| -2   | 395                  | 66.16   | 395      | 66.16       |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| 1  | 12                   | 2.01    | 407      | 68.17       |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| 2  | 190                  | 31.83   | 597      | 100.00      |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| f.   | Excessive discomfort | 1       | 2        |             |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>EX_DISCOM</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>-2</td> <td>395</td> <td>66.16</td> <td>395</td> <td>66.16</td> </tr> <tr> <td>1</td> <td>15</td> <td>2.51</td> <td>410</td> <td>68.68</td> </tr> <tr> <td>2</td> <td>187</td> <td>31.32</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table> |                      |         |          |             | EX_DISCOM  | Frequency | Percent | Cum Freq | Cum Percent | -2 | 395 | 66.16 | 395 | 66.16 | 1 | 15 | 2.51  | 410 | 68.68 | 2 | 187 | 31.32 | 597 | 100.00 |
| EX_DISCOM  | Frequency            | Percent | Cum Freq | Cum Percent |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| -2   | 395                  | 66.16   | 395      | 66.16       |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| 1  | 15                   | 2.51    | 410      | 68.68       |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| 2  | 187                  | 31.32   | 597      | 100.00      |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| g.   | Staffing constraints | 1       | 2        |             |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>STAFF_CON</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>-2</td> <td>395</td> <td>66.16</td> <td>395</td> <td>66.16</td> </tr> <tr> <td>1</td> <td>8</td> <td>1.34</td> <td>403</td> <td>67.50</td> </tr> <tr> <td>2</td> <td>194</td> <td>32.50</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>  |                      |         |          |             | STAFF_CON  | Frequency | Percent | Cum Freq | Cum Percent | -2 | 395 | 66.16 | 395 | 66.16 | 1 | 8  | 1.34  | 403 | 67.50 | 2 | 194 | 32.50 | 597 | 100.00 |
| STAFF_CON  | Frequency            | Percent | Cum Freq | Cum Percent |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| -2   | 395                  | 66.16   | 395      | 66.16       |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| 1  | 8                    | 1.34    | 403      | 67.50       |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| 2  | 194                  | 32.50   | 597      | 100.00      |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| h.   | Other                | 1↓      | 2        |             |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>VT_OTHER</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>-2</td> <td>395</td> <td>66.16</td> <td>395</td> <td>66.16</td> </tr> <tr> <td>1</td> <td>34</td> <td>5.70</td> <td>429</td> <td>71.86</td> </tr> <tr> <td>2</td> <td>168</td> <td>28.14</td> <td>597</td> <td>100.00</td> </tr> </tbody> </table>  |                      |         |          |             | VT_OTHER   | Frequency | Percent | Cum Freq | Cum Percent | -2 | 395 | 66.16 | 395 | 66.16 | 1 | 34 | 5.70  | 429 | 71.86 | 2 | 168 | 28.14 | 597 | 100.00 |
| VT_OTHER   | Frequency            | Percent | Cum Freq | Cum Percent |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| -2   | 395                  | 66.16   | 395      | 66.16       |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| 1  | 34                   | 5.70    | 429      | 71.86       |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| 2  | 168                  | 28.14   | 597      | 100.00      |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| Specify: _____   |                      |         |          |             |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |
| _____  |                      |         |          |             |            |           |         |          |             |    |     |       |     |       |   |    |       |     |       |   |     |       |     |        |

C2. Was the bladder filled to 300mL or to bladder capacity <300mL?

300mL ..... 1 → **SKIP TO C3**

Bladder capacity <300mL ..... 2

Passive fill trial..... 3 → **SKIP TO C3**

Trial not performed ..... 4 → **SKIP TO C6**

| BLAD_FILL | Frequency | Percent | Cum Freq | Cum Percent |
|-----------|-----------|---------|----------|-------------|
| -9        | 5         | 0.84    | 5        | 0.84        |
| 1         | 486       | 81.41   | 491      | 82.24       |
| 2         | 74        | 12.40   | 565      | 94.64       |
| 3         | 20        | 3.35    | 585      | 97.99       |
| 4         | 12        | 2.01    | 597      | 100.00      |

C2a. Specify bladder capacity: \_\_\_\_\_ mL

| Analysis Variable : MCC |        |       |      |         |                |        |                |         |
|-------------------------|--------|-------|------|---------|----------------|--------|----------------|---------|
| N                       | N Miss | Mean  | SD   | Minimum | Lower Quartile | Median | Upper Quartile | Maximum |
| 74                      | 0      | 240.5 | 32.0 | 160.0   | 220.0          | 240.0  | 270.0          | 290.0   |

| MCC | Frequency | Percent | Cum Freq | Cum Percent |
|-----|-----------|---------|----------|-------------|
| -9  | 5         | 0.96    | 5        | 0.96        |
| -2  | 518       | 99.04   | 523      | 100.00      |

C3. Voided volume \_\_\_\_\_ mL

C4. PVR \_\_\_\_\_ mL

| Analysis Variable : VOID_VOL |        |       |       |         |                |        |                |         |
|------------------------------|--------|-------|-------|---------|----------------|--------|----------------|---------|
| N                            | N Miss | Mean  | SD    | Minimum | Lower Quartile | Median | Upper Quartile | Maximum |
| 576                          | 0      | 240.9 | 114.5 | 0.0     | 200.0          | 260.0  | 300.0          | 535.0   |

| VOID_VOL | Frequency | Percent | Cum Freq | Cum Percent |
|----------|-----------|---------|----------|-------------|
| -9       | 9         | 42.86   | 9        | 42.86       |
| -2       | 12        | 57.14   | 21       | 100.00      |

| Analysis Variable : PVR |        |       |        |         |                |        |                |         |
|-------------------------|--------|-------|--------|---------|----------------|--------|----------------|---------|
| N                       | N Miss | Mean  | SD     | Minimum | Lower Quartile | Median | Upper Quartile | Maximum |
| 573                     | 0      | 73.70 | 127.41 | -150.00 | 0.00           | 30.00  | 100.00         | 750.00  |

| PVR | Frequency | Percent | Cum Freq | Cum Percent |
|-----|-----------|---------|----------|-------------|
| -9  | 7         | 29.17   | 7        | 29.17       |
| -2  | 13        | 54.17   | 20       | 83.33       |
| 999 | 4         | 16.67   | 24       | 100.00      |

C4a. Was the PVR calculated or measured? Calculated PVR ..... 1

Measured PVR..... 2

| PVR_METHOD | Frequency | Percent | Cum Freq | Cum Percent |
|------------|-----------|---------|----------|-------------|
| -9         | 7         | 1.17    | 7        | 1.17        |
| -2         | 12        | 2.01    | 19       | 3.18        |
| 1          | 471       | 78.89   | 490      | 82.08       |
| 2          | 107       | 17.92   | 597      | 100.00      |

C5. Outcome of the last voiding trial:

Pass ..... 1

Fail ..... 2

| LAST_VT_OUT | Frequency | Percent | Cum Freq | Cum Percent |
|-------------|-----------|---------|----------|-------------|
| -9          | 3         | 0.50    | 3        | 0.50        |
| -2          | 12        | 2.01    | 15       | 2.51        |
| 1           | 441       | 73.87   | 456      | 76.38       |
| 2           | 141       | 23.62   | 597      | 100.00      |

C6. Specify type of voiding management at discharge:

Urethral catheter..... 1

Clean intermittent self-catheterization (CISC)..... 2

Self-voiding ..... 3

| VM_DISCHARGE | Frequency | Percent | Cum Freq | Cum Percent |
|--------------|-----------|---------|----------|-------------|
| 1            | 114       | 19.10   | 114      | 19.10       |
| 2            | 29        | 4.86    | 143      | 23.95       |
| 3            | 454       | 76.05   | 597      | 100.00      |

**SECTION D: DISCHARGE INFORMATION**

SECTION D MAY BE COMPLETED BY A TOMUS CERTIFIED DATA COLLECTOR.

D1. Date of hospital admission:

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
 Month / Day / Year

| HOSP_ADMIT_days | Frequency | Percent | Cum Freq | Cum Percent |
|-----------------|-----------|---------|----------|-------------|
| -1              | 1         | 0.17    | 1        | 0.17        |
| 0               | 593       | 99.33   | 594      | 99.50       |
| 1               | 2         | 0.34    | 596      | 99.83       |
| 366             | 1         | 0.17    | 597      | 100.00      |

D2. Date of discharge:

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
 Month / Day / Year

| HOSP_DIS_days | Frequency | Percent | Cum Freq | Cum Percent |
|---------------|-----------|---------|----------|-------------|
| 0             | 387       | 64.82   | 387      | 64.82       |
| 1             | 178       | 29.82   | 565      | 94.64       |
| 2             | 27        | 4.52    | 592      | 99.16       |
| 3             | 2         | 0.34    | 594      | 99.50       |
| 4             | 1         | 0.17    | 595      | 99.66       |
| 10            | 1         | 0.17    | 596      | 99.83       |
| 366           | 1         | 0.17    | 597      | 100.00      |

D3. Was the patient discharged with medications specific to her recovery from the TOMUS surgery?

YES ..... 1

NO ..... 2 →SKIP TO D4

| DIS_MED | Frequency | Percent | Cum Freq | Cum Percent |
|---------|-----------|---------|----------|-------------|
| 1       | 589       | 98.66   | 589      | 98.66       |

| DIS_MED | Frequency | Percent | Cum Freq | Cum Percent |
|---------|-----------|---------|----------|-------------|
| 2       | 8         | 1.34    | 597      | 100.00      |

D3a. List medications by name. Include all for which a script was written including controlled and uncontrolled medications:

| MEDICATION | NAME  |
|------------|-------|
| 1          | _____ |
| 2          | _____ |
| 3          | _____ |

D4. Date TOMUS Postoperative Instructions Distributed to Patient: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Month Day Year

D4a. Initials of Study Staff who Distributed TOMUS Postoperative Instructions: \_\_\_\_\_

D5. Initials of Person Completing Sections C and D: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
(Initials) Month Day Year

| Analysis Variable : CD_COMP_Days |        |      |      |         |                |        |                |         |  |
|----------------------------------|--------|------|------|---------|----------------|--------|----------------|---------|--|
| N                                | N Miss | Mean | SD   | Minimum | Lower Quartile | Median | Upper Quartile | Maximum |  |
| 597                              | 0      | 7.7  | 24.1 | 0.0     | 0.0            | 1.0    | 6.0            | 411.0   |  |

**SECTION E: SURGEON'S SIGNATURE**

E1 is the form signed by the surgeon?

| PI SIG | Frequency | Percent | Cum Freq | Cum Percent |
|--------|-----------|---------|----------|-------------|
| 1      | 597       | 100.00  | 597      | 100.00      |

*I have reviewed the above-stated information and am confirming its accuracy with my signature below.*

Surgeon's Signature: \_\_\_\_\_ Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Month Day Year