

N A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY:

A1. STUDY ID #:

LABEL

A2. VISIT # F/U 12 Months TF12
F/U 24 Months TF24

Failure..... TFAI

VISIT	Frequency	Percent	Cum Freq	Cum Percent
TF12	538	52.59	538	52.59
TF24	485	47.41	1023	100.00

A3. DATE INTERVIEW COMPLETED: ___/___/___
MONTH DAY YEAR

A4. INTERVIEWER INITIALS: _____

A5. INTERVIEW TYPE? IN-PERSON 1
TELEPHONE 2

A6. FORM VERSION USED? ENGLISH..... 1
SPANISH..... 2

INT_TYPE	Frequency	Percent	Cum Freq	Cum Percent
1	979	95.70	979	95.70
2	44	4.30	1023	100.00

SECTION B: THE MESA INTERVIEW AND BLADDER AND BOWEL SYMPTOMS

This first set of questions asks about symptoms you may currently have related to urine leakage. For each question that I ask, please tell me the response that best represents how frequently you currently experience the symptom.

MESA PART I	Never	Rarely	Sometimes	Often																									
B1. Does coughing gently cause you to lose urine? (Would you say..)	0	1	2	3																									
<table border="1"> <thead> <tr> <th>MESA_STR_1</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td align="center">0</td> <td align="center">829</td> <td align="center">81.04</td> <td align="center">829</td> <td align="center">81.04</td> </tr> <tr> <td align="center">1</td> <td align="center">112</td> <td align="center">10.95</td> <td align="center">941</td> <td align="center">91.98</td> </tr> <tr> <td align="center">2</td> <td align="center">67</td> <td align="center">6.55</td> <td align="center">1008</td> <td align="center">98.53</td> </tr> <tr> <td align="center">3</td> <td align="center">15</td> <td align="center">1.47</td> <td align="center">1023</td> <td align="center">100.00</td> </tr> </tbody> </table>					MESA_STR_1	Frequency	Percent	Cum Freq	Cum Percent	0	829	81.04	829	81.04	1	112	10.95	941	91.98	2	67	6.55	1008	98.53	3	15	1.47	1023	100.00
MESA_STR_1	Frequency	Percent	Cum Freq	Cum Percent																									
0	829	81.04	829	81.04																									
1	112	10.95	941	91.98																									
2	67	6.55	1008	98.53																									
3	15	1.47	1023	100.00																									
B2. Does coughing hard cause you to lose urine? (Would you say...)	0	1	2	3																									

MESA_STR_2	Frequency	Percent	Cum Freq	Cum Percent
0	695	67.94	695	67.94
1	173	16.91	868	84.85
2	103	10.07	971	94.92
3	52	5.08	1023	100.00

B3. Does sneezing cause you to lose urine?

0 1 2 3

MESA_STR_3	Frequency	Percent	Cum Freq	Cum Percent
0	788	77.03	788	77.03
1	124	12.12	912	89.15
2	77	7.53	989	96.68
3	34	3.32	1023	100.00

B4. Does lifting things cause you to lose urine?

0 1 2 3

MESA_STR_4	Frequency	Percent	Cum Freq	Cum Percent
0	854	83.48	854	83.48
1	93	9.09	947	92.57
2	64	6.26	1011	98.83
3	12	1.17	1023	100.00

B5. Does bending cause you to lose urine?

0 1 2 3

MESA_STR_5	Frequency	Percent	Cum Freq	Cum Percent
0	923	90.22	923	90.22
1	60	5.87	983	96.09
2	35	3.42	1018	99.51
3	5	0.49	1023	100.00

B6. Does laughing cause you to lose urine?

0 1 2 3

MESA_STR_6	Frequency	Percent	Cum Freq	Cum Percent
0	880	86.02	880	86.02
1	81	7.92	961	93.94
2	45	4.40	1006	98.34
3	17	1.66	1023	100.00

B7. Does walking briskly or jogging cause you to lose urine?

0 1 2 3

MESA_STR_7	Frequency	Percent	Cum Freq	Cum Percent
0	870	85.04	870	85.04
1	69	6.74	939	91.79
2	64	6.26	1003	98.04
3	20	1.96	1023	100.00

B8. Does straining, if you are constipated, cause you to lose urine?

0 1 2 3

MESA_STR_8	Frequency	Percent	Cum Freq	Cum Percent
0	781	76.34	781	76.34
1	125	12.22	906	88.56
2	94	9.19	1000	97.75
3	23	2.25	1023	100.00

B9. Does getting up from a sitting to a standing position cause you to lose urine?

0 1 2 3

MESA_STR_9	Frequency	Percent	Cum Freq	Cum Percent
0	897	87.68	897	87.68
1	72	7.04	969	94.72
2	45	4.40	1014	99.12
3	9	0.88	1023	100.00

B10. DID THE PATIENT ANSWER “SOMETIMES OR OFTEN” TO ANY OF THE ITEMS IN B1 – B9?

YES..... 1

→FAILURE; COMPLETE FAILURE PROTOCOL

NO..... 2

MESA_RES	Frequency	Percent	Cum Freq	Cum Percent
1	251	24.54	251	24.54
2	772	75.46	1023	100.00

TOMMUS

MESA PART II	Never	Rarely	Sometimes	Often																									
B11. Some women receive very little warning and suddenly find that they are losing, or are about to lose urine beyond their control. How often does this happen to you? (Would you say....)	0	1	2	3																									
<table border="1"> <thead> <tr> <th>MESA_URG_1</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>618</td> <td>60.41</td> <td>618</td> <td>60.41</td> </tr> <tr> <td>1</td> <td>270</td> <td>26.39</td> <td>888</td> <td>86.80</td> </tr> <tr> <td>2</td> <td>111</td> <td>10.85</td> <td>999</td> <td>97.65</td> </tr> <tr> <td>3</td> <td>24</td> <td>2.35</td> <td>1023</td> <td>100.00</td> </tr> </tbody> </table>					MESA_URG_1	Frequency	Percent	Cum Freq	Cum Percent	0	618	60.41	618	60.41	1	270	26.39	888	86.80	2	111	10.85	999	97.65	3	24	2.35	1023	100.00
MESA_URG_1	Frequency	Percent	Cum Freq	Cum Percent																									
0	618	60.41	618	60.41																									
1	270	26.39	888	86.80																									
2	111	10.85	999	97.65																									
3	24	2.35	1023	100.00																									
B12. If you can't find a toilet or find that the toilet is occupied, and you have an urge to urinate, how often do you end up losing urine or wetting yourself? (Would you say....)	0	1	2	3																									
<table border="1"> <thead> <tr> <th>MESA_URG_2</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>639</td> <td>62.46</td> <td>639</td> <td>62.46</td> </tr> <tr> <td>1</td> <td>240</td> <td>23.46</td> <td>879</td> <td>85.92</td> </tr> <tr> <td>2</td> <td>105</td> <td>10.26</td> <td>984</td> <td>96.19</td> </tr> <tr> <td>3</td> <td>39</td> <td>3.81</td> <td>1023</td> <td>100.00</td> </tr> </tbody> </table>					MESA_URG_2	Frequency	Percent	Cum Freq	Cum Percent	0	639	62.46	639	62.46	1	240	23.46	879	85.92	2	105	10.26	984	96.19	3	39	3.81	1023	100.00
MESA_URG_2	Frequency	Percent	Cum Freq	Cum Percent																									
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1	240	23.46	879	85.92																									
2	105	10.26	984	96.19																									
3	39	3.81	1023	100.00																									
B13. Do you lose urine when you suddenly have the feeling that your bladder is very full?	0	1	2	3																									
<table border="1"> <thead> <tr> <th>MESA_URG_3</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>684</td> <td>66.86</td> <td>684</td> <td>66.86</td> </tr> <tr> <td>1</td> <td>191</td> <td>18.67</td> <td>875</td> <td>85.53</td> </tr> <tr> <td>2</td> <td>119</td> <td>11.63</td> <td>994</td> <td>97.17</td> </tr> <tr> <td>3</td> <td>29</td> <td>2.83</td> <td>1023</td> <td>100.00</td> </tr> </tbody> </table>					MESA_URG_3	Frequency	Percent	Cum Freq	Cum Percent	0	684	66.86	684	66.86	1	191	18.67	875	85.53	2	119	11.63	994	97.17	3	29	2.83	1023	100.00
MESA_URG_3	Frequency	Percent	Cum Freq	Cum Percent																									
0	684	66.86	684	66.86																									
1	191	18.67	875	85.53																									
2	119	11.63	994	97.17																									
3	29	2.83	1023	100.00																									
B14. Does washing your hands cause you to lose urine?	0	1	2	3																									
<table border="1"> <thead> <tr> <th>MESA_URG_4</th> <th>Frequency</th> <th>Percent</th> <th>Cum Freq</th> <th>Cum Percent</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>918</td> <td>89.74</td> <td>918</td> <td>89.74</td> </tr> <tr> <td>1</td> <td>58</td> <td>5.67</td> <td>976</td> <td>95.41</td> </tr> <tr> <td>2</td> <td>43</td> <td>4.20</td> <td>1019</td> <td>99.61</td> </tr> <tr> <td>3</td> <td>4</td> <td>0.39</td> <td>1023</td> <td>100.00</td> </tr> </tbody> </table>					MESA_URG_4	Frequency	Percent	Cum Freq	Cum Percent	0	918	89.74	918	89.74	1	58	5.67	976	95.41	2	43	4.20	1019	99.61	3	4	0.39	1023	100.00
MESA_URG_4	Frequency	Percent	Cum Freq	Cum Percent																									
0	918	89.74	918	89.74																									
1	58	5.67	976	95.41																									
2	43	4.20	1019	99.61																									
3	4	0.39	1023	100.00																									
B15. Does cold weather cause you to lose urine?	0	1	2	3																									

MESA_URG_5	Frequency	Percent	Cum Freq	Cum Percent
0	939	91.79	939	91.79
1	44	4.30	983	96.09
2	32	3.13	1015	99.22
3	8	0.78	1023	100.00

B16. Does drinking cold beverages cause you to lose urine? 0 1 2 3

MESA_URG_6	Frequency	Percent	Cum Freq	Cum Percent
0	979	95.70	979	95.70
1	28	2.74	1007	98.44
2	15	1.47	1022	99.90
3	1	0.10	1023	100.00

BLADDER AND BOWEL SYMPTOMS

B17. Compared to before your surgery for urinary incontinence, have you had an increase in your frequency of urination?

YES..... 1
NO..... 2

UR_FREQ	Frequency	Percent	Cum Freq	Cum Percent
1	170	16.62	170	16.62
2	853	83.38	1023	100.00

B18. Do you **currently** have to...

YES NO

a. ... strain to urinate? 1 2

STRAIN_UR	Frequency	Percent	Cum Freq	Cum Percent
1	62	6.06	62	6.06
2	961	93.94	1023	100.00

b. ... bend forward to urinate?..... 1 2

BEND_UR	Frequency	Percent	Cum Freq	Cum Percent
1	145	14.17	145	14.17
2	878	85.83	1023	100.00

c. ... lean back to urinate?..... 1 2

LEAN_UR	Frequency	Percent	Cum Freq	Cum Percent
1	53	5.18	53	5.18
2	970	94.82	1023	100.00

d. ... stand up to urinate?..... 1 2

STAND_UR	Frequency	Percent	Cum Freq	Cum Percent
1	16	1.56	16	1.56
2	1007	98.44	1023	100.00

e. ... press on your bladder to urinate?..... 1 2

PRESS_UR	Frequency	Percent	Cum Freq	Cum Percent
1	23	2.25	23	2.25
2	1000	97.75	1023	100.00

f. ... push on the vagina or perineum to empty your bladder?..... 1 2

PUSH_UR	Frequency	Percent	Cum Freq	Cum Percent
1	18	1.76	18	1.76
2	1005	98.24	1023	100.00

g. ... do anything else to urinate?..... 1↓ 2

OTH_ACC_UR	Frequency	Percent	Cum Freq	Cum Percent
1	33	3.23	33	3.23
2	990	96.77	1023	100.00

B18h. If yes, describe: _____

B19. How bothered are you by the way you now urinate compared to how you urinated prior to the surgery? Would you say...

- Not at all bothered..... 1
- Slightly bothered..... 2
- Moderately bothered..... 3
- Greatly bothered 4

UR_BOTH	Frequency	Percent	Cum Freq	Cum Percent
1	834	81.52	834	81.52
2	147	14.37	981	95.89
3	33	3.23	1014	99.12
4	9	0.88	1023	100.00

B20. Would you describe your **current** urine stream as...

YES NO

a. ... a steady stream of urine? 1 2

STEADY_STR	Frequency	Percent	Cum Freq	Cum Percent
1	892	87.19	892	87.19
2	131	12.81	1023	100.00

b. ... a slow stream of urine? 1 2

SLOW_STR	Frequency	Percent	Cum Freq	Cum Percent
1	315	30.79	315	30.79
2	708	69.21	1023	100.00

c. ... a spurting, splitting or spraying stream of urine? 1 2

SPURT_STR	Frequency	Percent	Cum Freq	Cum Percent
1	241	23.56	241	23.56
2	782	76.44	1023	100.00

d. ... a hesitating stream of urine (stops and starts)? 1 2

HEIST_STR	Frequency	Percent	Cum Freq	Cum Percent
1	262	25.61	262	25.61
2	761	74.39	1023	100.00

e. ... dribbling after you have finished urinating?..... 1 2

DRIB_STR	Frequency	Percent	Cum Freq	Cum Percent
1	389	38.03	389	38.03
2	634	61.97	1023	100.00

f. ... some other description?..... 1↓ 2

B20g. If yes, describe: _____

OTH_STR	Frequency	Percent	Cum Freq	Cum Percent
1	40	3.91	40	3.91
2	983	96.09	1023	100.00

B21. Do you currently experience a feeling of incomplete bladder emptying?

YES..... 1

NO..... 2

INC_EMPTY	Frequency	Percent	Cum Freq	Cum Percent
1	233	22.78	233	22.78
2	790	77.22	1023	100.00

B22. How would you describe the **time it takes** to urinate now, compared to before your surgery? Would you say there's been no change, or does it seem to take more or less time to urinate now compared to before the surgery?

NO CHANGE..... 1

TAKES MORE TIME TO URINATE 2

TAKES LESS TIME TO URINATE 3

UR_TIME	Frequency	Percent	Cum Freq	Cum Percent
1	491	48.00	491	48.00
2	390	38.12	881	86.12
3	142	13.88	1023	100.00

B23. These next few questions ask about any symptoms of bowel incontinence you may have.

Do you have to strain to have a bowel movement? YES..... 1
 NO..... 2 ➔ SKIP TO B24

STR_BM	Frequency	Percent	Cum Freq	Cum Percent
1	375	36.66	375	36.66
2	648	63.34	1023	100.00

B23a. How **often** do you have to strain to have a bowel movement? Would you say....

Less than or equal to 25% of the time? 1
 More than 25% of the time? 2

OFT_STR_BM	Frequency	Percent	Cum Freq	Cum Percent
.	648	.	.	.
1	248	66.13	248	66.13
2	127	33.87	375	100.00

B24. Do you have leaking or loss of control of gas? YES 1
 NO 2 ➔ SKIP TO B25

GAS_LK	Frequency	Percent	Cum Freq	Cum Percent
1	401	39.20	401	39.20
2	622	60.80	1023	100.00

B24a. How **often** does this happen? Would you say....

less than once a month? 1
 more than once a month but less than once a week? 2
 more than once a week but less than every day? 3
 every day? 4

OFT_GAS_LK	Frequency	Percent	Cum Freq	Cum Percent
.	623	.	.	.
1	47	11.75	47	11.75
2	83	20.75	130	32.50
3	161	40.25	291	72.75
4	109	27.25	400	100.00

B25. Do you have leaking or loss of control of liquid stool? YES 1
 NO 2 ➔ SKIP TO B26

LIQ_STOOL_LK	Frequency	Percent	Cum Freq	Cum Percent
1	109	10.65	109	10.65
2	914	89.35	1023	100.00

B25a. How **often** does this happen? Would you say....

- less than once a month?..... 1
- more than once a month but less than once a week? 2
- more than once a week but less than every day?..... 3
- every day?..... 4

OFT_LIQ_LK	Frequency	Percent	Cum Freq	Cum Percent
.	914	.	.	.
1	63	57.80	63	57.80
2	27	24.77	90	82.57
3	17	15.60	107	98.17
4	2	1.83	109	100.00



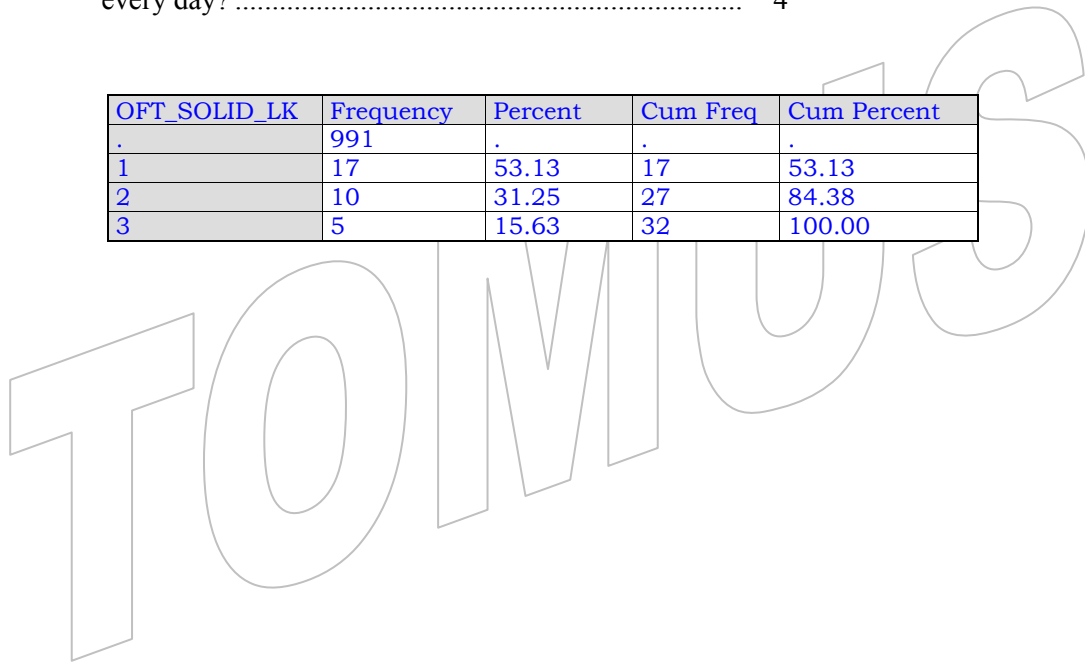
B26. Do you have leaking or loss of control of solid stool? YES..... 1
 NO..... 2 → **SKIP TO SECTION C**

SOL_STOOL_LK	Frequency	Percent	Cum Freq	Cum Percent
1	32	3.13	32	3.13
2	991	96.87	1023	100.00

B26a. How **often** does this happen? Would you say....

less than once a month?..... 1
 more than once a month but less than once a week?..... 2
 more than once a week but less than every day?..... 3
 every day? 4

OFT_SOLID_LK	Frequency	Percent	Cum Freq	Cum Percent
.	991	.	.	.
1	17	53.13	17	53.13
2	10	31.25	27	84.38
3	5	15.63	32	100.00



SECTION C: HEALTH SERVICES UTILIZATION

IDENTIFY THE REFERENCE DATE FOR USE IN SECTION C:

DATE OF THE LAST STUDY VISIT (TF06 OR TF12) FROM THE VCS:

____/____/____
Month Day Year

This next series of questions asks about any health care or treatments that you may have received since your last study visit.

C1. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **PHYSICIAN VISITS RELATED TO SURGERY, OR TREATMENT OF URINARY SYMPTOMS INCLUDING URINARY TRACT INFECTIONS OR INCONTINENCE** SINCE THE LAST FOLLOW-UP VISIT? LOOK SPECIFICALLY FOR REPORTS OF COMPLICATIONS. ASK,

Have you seen a doctor (nurse practitioner, physician’s assistant) for any reason related to your TOMUS surgery or for treatment of any urinary symptoms including urinary tract infections or urinary incontinence since your last TOMUS study visit (on DATE OF LAST VISIT)?

YES 1

NO 2 → **SKIP TO C3**

PHYS_VISIT	Frequency	Percent	Cum Freq	Cum Percent
1	172	16.81	172	16.81
2	851	83.19	1023	100.00

C2. DATES OF AND REASONS FOR ANY **PHYSICIAN VISITS FOR URINARY SYMPTOMS OR TOMUS SURGERY**; ASK,

What was (were) the (approximate) date(s) and reason(s) for those physician (NP, PA) visit(s) since your last TOMUS study visit?

SOURCE CODES: 1= PATIENT; 2= MEDICAL RECORD; 3= BOTH PT AND RECORD, 5= PT REPORT AND SENT FOR MR. ↓

	a.	b.	c.
	<u>APPROXIMATE DATE</u>	<u>REASON FOR THE VISIT</u>	<u>SOURCE CODE</u>
1	____/____/____	_____	____
2	____/____/____	_____	____
3	____/____/____	_____	____

C3. IS THERE EVIDENCE OF ANY **PHYSICIAN VISITS FOR ANY OTHER REASON** SINCE THE LAST FOLLOW-UP VISIT? LOOK SPECIFICALLY FOR REPORTS OF COMPLICATIONS. ASK,

Have you seen a doctor (nurse practitioner, physician’s assistant) for any other reason since your last TOMUS study visit (on DATE OF LAST VISIT)?

YES 1

NO 2 → **SKIP TO C5**

O_PHYS_VISIT	Frequency	Percent	Cum Freq	Cum Percent
1	850	83.09	850	83.09
2	173	16.91	1023	100.00

TOMMUS

C4. DATES OF AND REASONS FOR ANY OTHER PHYSICIAN VISITS; ASK,

What was (were) the (approximate) date(s) and reason(s) for those physician (NP, PA) visit(s)?

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ↓

	a.	b.	c.
	<u>APPROXIMATE DATE</u>	<u>REASON FOR THE VISIT</u>	<u>SOURCE CODE</u>
1	___/___/_____	_____	___
2	___/___/_____	_____	___
3	___/___/_____	_____	___

C5. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY EMERGENCY ROOM VISITS SINCE THE LAST FOLLOW-UP VISIT? ASK,

Have you been to an emergency room for any reason since your last TOMUS study visit (on DATE OF LAST VISIT)?

YES 1

NO 2 → SKIP TO C7

ER VISIT	Frequency	Percent	Cum Freq	Cum Percent
1	135	13.20	135	13.20
2	888	86.80	1023	100.00

C6. DATES OF AND REASONS FOR ANY EMERGENCY ROOM VISIT(S), ASK,

What was (were) the (approximate) date(s) and reason(s) for the emergency room visit(s) since your last TOMUS study visit?

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ↓

	a.	b.	c.
	<u>APPROXIMATE DATE</u>	<u>REASON FOR THE ER VISIT</u>	<u>SOURCE CODE</u>
1	___/___/_____	_____	___
2	___/___/_____	_____	___
3	___/___/_____	_____	___

C7. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **NEW SURGERIES** SINCE THE LAST FOLLOW-UP VISIT? ASK,

Have you had any new surgery since your last TOMUS study visit (on DATE OF LAST VISIT)?

YES 1

NO 2 → **SKIP TO C9**

NEW SURG	Frequency	Percent	Cum Freq	Cum Percent
1	147	14.37	147	14.37
2	876	85.63	1023	100.00

C8. DATES OF AND DESCRIPTION OF NEW SURGERIES. ASK,

Tell me more about these surgeries.

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ↓

	<u>a.</u>	<u>b.</u>	<u>c.</u>	<u>d.</u>	<u>e.</u>
	<u>NAME OF SURGERY</u>	<u>SURGICAL CODE</u>	<u>SPECIFY (IF SURGICAL CODE = 07)</u>	<u>DATE OF SURGERY</u>	<u>SOURCE CODE</u>
1		_____		____/____/____	_____
2		_____		____/____/____	_____
3		_____		____/____/____	_____

C9. OTHER THAN ANY DESCRIBED ABOVE IN C8, DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **HOSPITAL ADMISSIONS** SINCE THE LAST FOLLOW-UP VISIT? ASK,

Have you been hospitalized for any (other) reason since your last TOMUS study visit (on DATE OF LAST VISIT)?

YES 1

NO 2 → **SKIP TO SECTION D**

HOS ADMIT	Frequency	Percent	Cum Freq	Cum Percent
1	77	7.53	77	7.53
2	946	92.47	1023	100.00

C10. DATES OF AND REASONS FOR **HOSPITAL ADMISSIONS**. ASK,

What was (were) the (approximate) date(s) and reason for each hospitalization that occurred since your last TOMUS study visit?

SOURCE CODES: 1 = PATIENT; 2 = MEDICAL RECORD; 3 = BOTH PT AND RECORD, 5 = PT REPORT AND SENT FOR MR. ↓

	<u>a.</u>	<u>b.</u>	<u>c.</u>
	<u>APPROXIMATE DATE</u>	<u>REASON FOR HOSPITALIZATION</u>	<u>SOURCE CODE</u>
1	____/____/____	_____	_____

Affix ID Label Here

2	___ / ___ / _____	_____	___
3	___ / ___ / _____	_____	___

REMINDER: COMPLETE ADVERSE EVENT FORM (F391) AS NECESSARY

TOMMUS

SECTION D: SOURCE DOCUMENT REVIEW ATTESTATION

D1. Initials of Interviewer/Data Collector who completed a thorough review of all source documents (i.e. inpatient medical records, clinic charts, etc.) for any pertinent study information since the last study visit (e.g. adverse events, retreatments, interim visits, etc.): _____

D2. Date Review Completed: _____ / _____ / _____
Month Day Year

D3. Signature of Data Collector Completing D1: _____



Attachment

SURGERY CODES	
00	Urethrolisis/Tape Takedown
01	Abdominoplasty
02	Anterior repair
03	Cesarean delivery
04	Femoral hernia repair
05	Hysterectomy
06	Inguinal hernia repair
07	Laparoscopy
08	Posterior repair
09	Removal of an ectopic pregnancy
10	Removal of an ovarian cyst
11	Removal of both ovaries
12	Removal of one ovary
13	Supracervical hysterectomy
14	Tubal ligation
15	D and C (dilatation and curettage)
16	Colpopexy (abdominal)
17	Colpopexy (vaginal)
31	Enterocoele repair
32	Vaginal vault suspension
18	UNKNOWN TYPE
19	OTHER

SURGERY FOR UI CODES	
20	Anterior repair, Kelly plication, suburethral plication
21	Collagen injection
22	Durasphere injection
23	Other periurethral bulking agent
24	Laparoscopic Burch colposuspension
25	Marshall-Marchetti-Krantz (MMK) bladder suspension
26	Needle suspensions: Raz, Pereyra, Gittes
27	Open Burch colposuspension
28	Sling procedure (autologous or cadaveric)
29	Sling procedures (synthetic material)
30	Tightening of previous sling
38	UNKNOWN TYPE
39	OTHER

TREATMENT CODES	
40	Medicine (drug treatment)
41	Bladder training (including behavior changes involving the timing of urination or changes in fluid intake)
42	Pelvic muscle exercises (Kegel exercises)
43	Electrical stimulation
44	Electromagnetic therapy
45	Biofeedback
46	Acupuncture or other alternative medicine techniques
58	UNKNOWN TYPE
59	OTHER TYPE

SLING REVISION CODES	
60	Tape loosening
61	Tape incision