

SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY:

A1. STUDY ID #:

LABEL

A2. VISIT # F/U 6 Months.....TF06

Failure..... TFAI

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

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
B2. Does coughing hard cause you to lose urine? (Would you say...)	0	1	2	3
B3. Does sneezing cause you to lose urine?	0	1	2	3
B4. Does lifting things cause you to lose urine?	0	1	2	3
B5. Does bending cause you to lose urine?	0	1	2	3
B6. Does laughing cause you to lose urine?	0	1	2	3
B7. Does walking briskly or jogging cause you to lose urine?	0	1	2	3
B8. Does straining, if you are constipated, cause you to lose urine?	0	1	2	3
B9. Does getting up from a sitting to a standing position cause you to lose urine?	0	1	2	3

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 PART II	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>
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
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
B13. Do you lose urine when you suddenly have the feeling that your bladder is very full?	0	1	2	3
B14. Does washing your hands cause you to lose urine?	0	1	2	3
B15. Does cold weather cause you to lose urine?	0	1	2	3
B16. Does drinking cold beverages cause you to lose urine?	0	1	2	3

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

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

	YES	NO
a. ... strain to urinate?	1	2
b. ... bend forward to urinate?	1	2
c. ... lean back to urinate?	1	2
d. ... stand up to urinate?	1	2
e. ... press on your bladder to urinate?	1	2
f. ... push on the vagina or perineum to empty your bladder?	1	2
g. ... do anything else to urinate?	1↓	2

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

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

YES	NO
-----	----

- | | | |
|--|---|---|
| a. ... a steady stream of urine? | 1 | 2 |
| b. ... a slow stream of urine?..... | 1 | 2 |
| c. ... a spurting, splitting or spraying stream of urine?..... | 1 | 2 |
| d. ... a hesitating stream of urine (stops and starts)? | 1 | 2 |
| e. ... dribbling after you have finished urinating?..... | 1 | 2 |
| f. ... some other description?..... | 1 | 2 |

B20g. If yes, describe: _____

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

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

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

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

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

B24. Do you have leaking or loss of control of gas? YES 1

NO 2 → SKIP TO B25

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

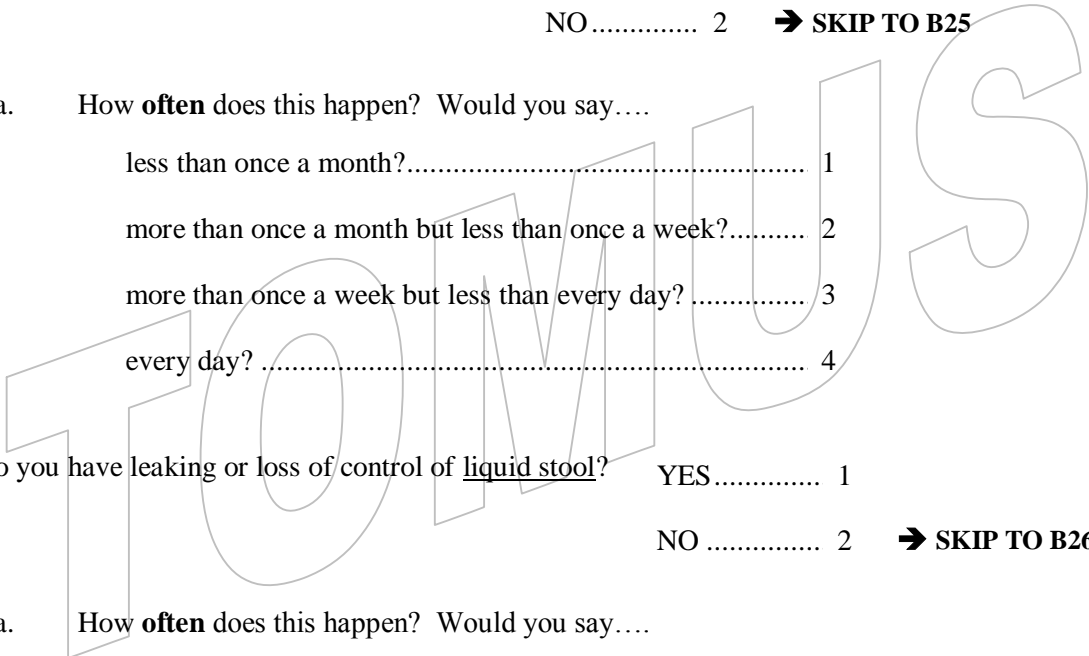
less than once a month?..... 1
more than once a month but less than once a week?..... 2
more than once a week but less than every day? 3
every day? 4

B25. Do you have leaking or loss of control of liquid stool? YES 1

NO 2 → SKIP TO B26

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



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

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

SECTION C: RESUMPTION OF ACTIVITIES

C1. Have you returned to full normal activities of daily life (including work, if applicable) since your surgery?
YES 1
NO 2 → SKIP TO C2

C1a. (Approximately) how many days did it take you to return to full normal activities of daily life (including work, if applicable) after surgery?
_____ DAYS

C1b. How many **paid** workdays did you take off after surgery?
_____ DAYS → SKIP TO D1
(IF UNEMPLOYED OR RETIRED, CODE -1)

C2. If you have not returned to work, is that because your work includes activities such as heavy lifting, which you were advised not to do?
YES 1
NO 2
(IF UNEMPLOYED OR RETIRED, CODE -1)

SECTION D: HEALTH SERVICES UTILIZATION

IDENTIFY THE REFERENCE DATE FOR USE IN SECTION D:

DATE OF THE TF6W STUDY VISIT 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.

D1. 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 6 WEEK 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 6 WEEK VISIT)?

- YES 1
- NO 2 → **SKIP TO D3**

D2. 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	____/____/____	_____	____

D3. IS THERE EVIDENCE OF ANY **PHYSICIAN VISITS FOR ANY OTHER REASON** SINCE THE 6 WEEK 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 6 WEEK VISIT)?

- YES 1
- NO 2 → **SKIP TO D5**

D4. 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	___/___/_____	_____	___

D5. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY EMERGENCY ROOM VISITS SINCE THE 6 WEEK FOLLOW-UP VISIT? ASK,

Have you been to an emergency room for any reason since your last TOMUS study visit (on DATE OF 6 WEEK VISIT)?

YES 1

NO 2 → **SKIP TO D7**

D6. 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	___/___/_____	_____	___

D7. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **NEW SURGERIES** SINCE THE 6 WEEK FOLLOW-UP VISIT? ASK,

Have you had any new surgery since your last TOMUS study visit (on DATE OF 6 WEEK VISIT)?

YES 1

NO 2 → **SKIP TO D9**

D8. 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</u> (IF SURGICAL CODE = 07)	<u>DATE OF SURGERY</u>	<u>SOURCE CODE</u>
1		____		____ / ____ / ____	____
2		____		____ / ____ / ____	____
3		____		____ / ____ / ____	____

D9. OTHER THAN ANY DESCRIBED ABOVE IN D8, DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **HOSPITAL ADMISSIONS** SINCE THE 6 WEEK FOLLOW-UP VISIT? ASK,

Have you been hospitalized for any (other) reason since your last TOMUS study visit (on DATE OF 6 WEEK VISIT)?

YES 1

NO 2 → **SKIP TO SECTION E**

D10. 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	____ / ____ / ____		____
2	____ / ____ / ____		____
3	____ / ____ / ____		____

REMINDER: COMPLETE ADVERSE EVENT FORM (F391) AS NECESSARY

SECTION E: SOURCE DOCUMENT REVIEW ATTESTATION

E1. 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.): _____

E2. Date Review Completed: _____ / _____ / _____
Month Day Year

E3. Signature of Data Collector Completing E1: _____

TOMMUS

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