

SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY:

A1. STUDY ID #:	LABEL	A2. VISIT # F/U 6 Weeks TF6W
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	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>
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

MESA PART II	<i>Never</i>	<i>Rarely</i>	<i>Sometimes</i>	<i>Often</i>
B10. 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
B11. 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
B12. Do you lose urine when you suddenly have the feeling that your bladder is very full?	0	1	2	3
B13. Does washing your hands cause you to lose urine?	0	1	2	3
B14. Does cold weather cause you to lose urine?	0	1	2	3
B15. Does drinking cold beverages cause you to lose urine?	0	1	2	3

BLADDER AND BOWEL SYMPTOMS

B16. Compared to before your surgery for urinary incontinence, have you had an increase in your frequency of urination?

YES 1

NO 2

B17. 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

B17h. If yes, describe: _____

B18. 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

B19. 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

B19g. If yes, describe: _____

B20. Do you currently experience a feeling of incomplete bladder emptying?

- YES 1
- NO 2

B21. 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

B22. 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 B23

B22a. 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

B23. Do you have leaking or loss of control of gas? YES..... 1
NO 2 → SKIP TO B24

B23a. 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

B24. Do you have leaking or loss of control of liquid stool? 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 solid stool? YES 1
NO 2 → SKIP TO SECTION C

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

SECTION C: NEUROLOGIC SYMPTOMS

INSTRUCTIONS: We also want to know if you have any numbness or weakness in your lower abdomen or your pelvic area or in your lower extremities.

C1. First, I'll ask about numbness. Do you have any **numbness** in your lower abdomen or your pelvic area or your legs?

YES..... 1* NO 2 ➔ **SKIP TO C2**

REMINDER: COMPLETE ADVERSE EVENT FORM (F391) AS NECESSARY

SHOW ATTACHED BODY MAPS 1, 2, 4, AND 6 FOR MARKING NUMBNESS:

Here are 4 pictures of those areas. The specific areas we're asking about are circled on the pictures. Take a minute to look at the pictures and mark Xs to show where you feel numbness.

WHEN THE PATIENT COMPLETES HER MARKINGS, INSPECT THE PICTURES AND COMPLETE C1a-e.

C1a. DID THE PATIENT MARK ANY Xs IN THE **SUPRAPUBIC** AREA (PICTURE #1)?

YES..... 1 NO 2 ➔ **SKIP TO C1b**

C1ai. SHOW PICTURE #1: How bothersome is the numbness in **this** location? Would you say...

- not at all bothersome..... 1
- slightly bothersome..... 2
- moderately bothersome..... 3
- greatly bothersome..... 4

C1b. DID THE PATIENT MARK ANY Xs IN THE **GROIN** AREA? (PICTURE #2)

YES..... 1 NO 2 ➔ **SKIP TO C1c**

C1bi. SHOW PICTURE #2: How bothersome is the numbness in **this** location? Would you say...

- not at all bothersome..... 1
- slightly bothersome..... 2
- moderately bothersome..... 3
- greatly bothersome..... 4

C1c. DID THE PATIENT MARK ANY Xs IN THE VULVAR AREA? (PICTURE #4)

YES..... 1 NO..... 2 → SKIP TO C1d

C1ci. SHOW PICTURE #4: How bothersome is the numbness in **this** location? Would you say...

- not at all bothersome..... 1
- slightly bothersome..... 2
- moderately bothersome..... 3
- greatly bothersome..... 4

C1d. DID THE PATIENT MARK ANY Xs IN THE UPPER LEG AREA? (PICTURE #6)

YES..... 1 NO..... 2 → SKIP TO C1e

C1di. SHOW PICTURE #6 FOR NUMBNESS:

How bothersome is the numbness in **this** location? Would you say...

- not at all bothersome..... 1
- slightly bothersome..... 2
- moderately bothersome..... 3
- greatly bothersome..... 4

C1e. DID THE PATIENT MARK ANY Xs IN THE LOWER LEG AREA? (PICTURE #6)

YES..... 1 NO..... 2 → SKIP TO C2

C1ei. SHOW PICTURE #6 FOR NUMBNESS:

How bothersome is the numbness in **this** location? Would you say...

- not at all bothersome..... 1
- slightly bothersome..... 2
- moderately bothersome..... 3
- greatly bothersome..... 4

C2. Next, I'll ask about weakness. Do you have any **weakness** in your legs?

YES..... 1* NO..... 2 → **SKIP TO SECTION D**

REMINDER: COMPLETE ADVERSE EVENT FORM (F391) AS NECESSARY

SHOW PICTURE # 6 FOR WEAKNESS: Here is a (another) picture of the legs. Look at the picture and mark Xs to show where you feel weakness.

WHEN THE PATIENT COMPLETES HER MARKINGS, INSPECT THE PICTURE AND FINISH C2 a-b.

C2a. DID THE PATIENT MARK ANY Xs IN THE **UPPER LEG** AREA?

YES..... 1 NO..... 2 → **SKIP TO C2b**

C2ai. SHOW PICTURE #6 FOR WEAKNESS: POINT TO Xs MARKED ON UPPER LEG.

How bothersome is the weakness in **this** location? Would you say...

- not at all bothersome..... 1
- slightly bothersome..... 2
- moderately bothersome..... 3
- greatly bothersome..... 4

C2b. DID THE PATIENT MARK ANY Xs IN THE **LOWER LEG** AREA?

YES..... 1 NO..... 2 → **SKIP TO D1**

C2bi. SHOW PICTURE #6 FOR WEAKNESS: POINT TO Xs MARKED ON LOWER LEG.

How bothersome is the weakness in **this** location? Would you say...

- not at all bothersome..... 1
- slightly bothersome..... 2
- moderately bothersome..... 3
- greatly bothersome..... 4

SECTION D: RESUMPTION OF ACTIVITIES

D1. Have you returned to full normal activities of daily life (including work, if applicable) since your surgery?

YES 1

NO 2 → **SKIP TO D2**

D1a. (Approximately) how many days did it take you to return to full normal activities of daily life (including work, if applicable) after surgery?

___ ___ DAYS

D1b. How many **paid** workdays did you take off after surgery?

___ ___ DAYS → **SKIP TO E1**

(IF UNEMPLOYED OR RETIRED, CODE -1)

D2. 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 E: HEALTH SERVICES UTILIZATION

IDENTIFY THE REFERENCE DATE FOR USE IN SECTION E:

DATE OF THE 2-WEEK FU 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.

E1. 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 2-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 2-WEEK VISIT)?

- YES 1
- NO 2 → **SKIP TO E3**

E2. 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	____ / ____ / _____	_____	____

E3. IS THERE EVIDENCE OF ANY **PHYSICIAN VISITS FOR ANY OTHER REASON** SINCE THE 2-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 2-WEEK VISIT)?

- YES 1
- NO 2 → **SKIP TO E5**

E4. 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	___ / ___ / _____	_____	___

E5. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY ONGOING NON-SURGICAL TREATMENT FOR URINARY INCONTINENCE? ASK,

Have you used or received any **non-surgical treatment(s)** for symptoms related to urine leakage / urinary incontinence since your last study visit (on DATE OF 2-WEEK VISIT)?

(PROBE: This would include any medications that you take or any bladder training programs that you follow or pelvic muscle exercises that you do; it would also include treatments you might receive such as acupuncture, biofeedback, electrical stimulation, or electromagnetic therapy.)

- YES 1
 NO 2 **→ SKIP TO E7**

E6. RECORD THE NAMES, CODES AND DATES OF ALL NON-SURGICAL TREATMENTS FOR UI. SAY,

Tell me more about that / those... (non-surgical treatments for urinary incontinence).

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

	a.	b.	c.	d.
	<u>TYPE OF TREATMENT</u>	<u>TREATMENT CODE*</u>	<u>DATES OF TREATMENT</u>	<u>SOURCE CODE</u>
1.		_____	FROM: ___ / ___ / _____ TO: ___ / ___ / _____	___
2.		_____	FROM: ___ / ___ / _____ TO: ___ / ___ / _____	___
3.		_____	FROM: ___ / ___ / _____ TO: ___ / ___ / _____	___

*** Medications must also be recorded on the Medication Audit completed for this visit.**

E7. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **EMERGENCY ROOM VISITS** SINCE HER 2-WEEK FOLLOW-UP VISIT? ASK,
 Have you been to an emergency room for any reason since your last TOMUS study visit (on DATE OF 2-WEEK VISIT)?

- YES 1
 NO 2 → **SKIP TO E9**

E8. 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	___ / ___ / _____	_____	___

E9. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **NEW ABDOMINAL OR PELVIC SURGERY** SINCE HER 2-WEEK FOLLOW-UP VISIT? ASK,
 Have you had any new abdominal or pelvic surgery since your last TOMUS study visit (on DATE OF 2-WEEK VISIT)?

- YES 1
 NO 2 → **SKIP TO E11**

E10. DATES OF AND DESCRIPTION OF NEW ABDOMINAL OR PELVIC 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.		___ ___		___ ___ / ___ ___ / _____	___

E11. OTHER THAN ANY DESCRIBED ABOVE IN E10, DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **HOSPITAL ADMISSIONS** SINCE HER 2 WEEK FOLLOW-UP VISIT? ASK,

Have you been hospitalized for any (other) reason since your last TOMUS study visit (on DATE OF 2-WEEK VISIT)?

YES 1

NO 2 → **SKIP TO E13**

E12. 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	___ / ___ / _____	_____	___

E13. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **ANTIBIOTICS** PRESCRIBED SINCE HER 2-WEEK FOLLOW-UP VISIT? ASK ABOUT ANTIBIOTICS SHE REPORTED TAKING AT HER 2-WEEK FOLLOW-UP VISIT. ASK,

Since your last TOMUS study visit, has a doctor prescribed any antibiotics (on DATE OF 2-WEEK VISIT)?

YES 1

NO 2 → **SKIP TO SECTION F**

E14. RECORD EACH ANTIBIOTIC BY NAME

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>ANTIBIOTIC NAME*</u> <u>(PRINT NAME PRECISELY)</u>	<u>NUMBER OF DAYS TAKEN</u>	<u>IS THE PATIENT STILL TAKING THIS MEDICATION?</u>	<u>REASON PRESCRIBED</u>	<u>SOURCE CODE</u>
1		___ ___	YES1 NO..... 2		___
2		___ ___	YES1 NO..... 2		___
3		___ ___	YES1 NO..... 2		___

***Medications must also be recorded on the Medication Audit completed for this visit.**

REMINDER: COMPLETE ADVERSE EVENT FORM (F391) AS NECESSARY

SECTION F: SOURCE DOCUMENT REVIEW ATTESTATION

F1. 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.): _____

F2. Date Review Completed: _____ / _____ / _____
Month Day Year

F3. Signature of Data Collector Completing F1: _____

TOMMUS

Attachment

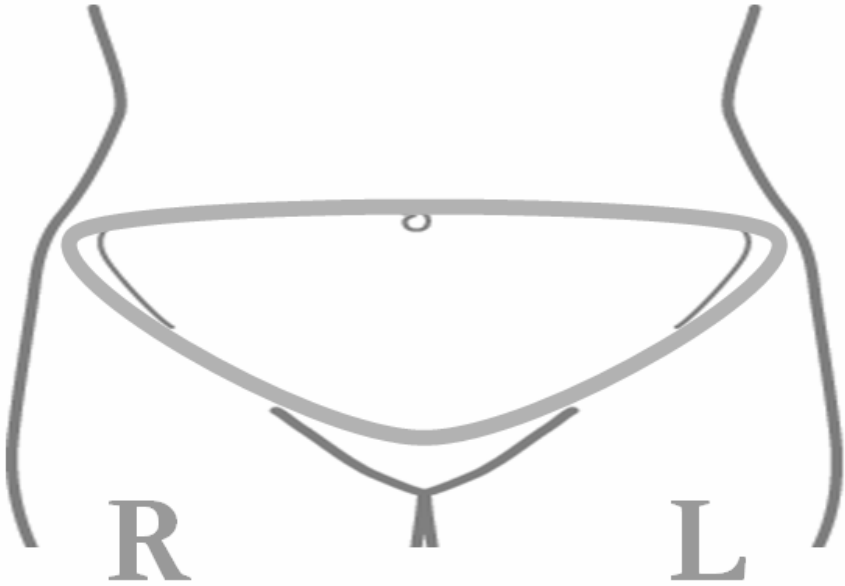
SURGERY CODES	
00	Urethrolisis/Tape Takedown
01	Abdominoplasty
02	Anterior repair
03	Cesarean delivery
04	Femoral hernia repair
05	Hysterectomy
06	Inguinal hernia repair
07	Laparoscopy
08	Posterior repair
09	Removal of an ectopic pregnancy
10	Removal of an ovarian cyst
11	Removal of both ovaries
12	Removal 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

SLING REVISION CODES	
60	Tape loosening
61	Tape incision

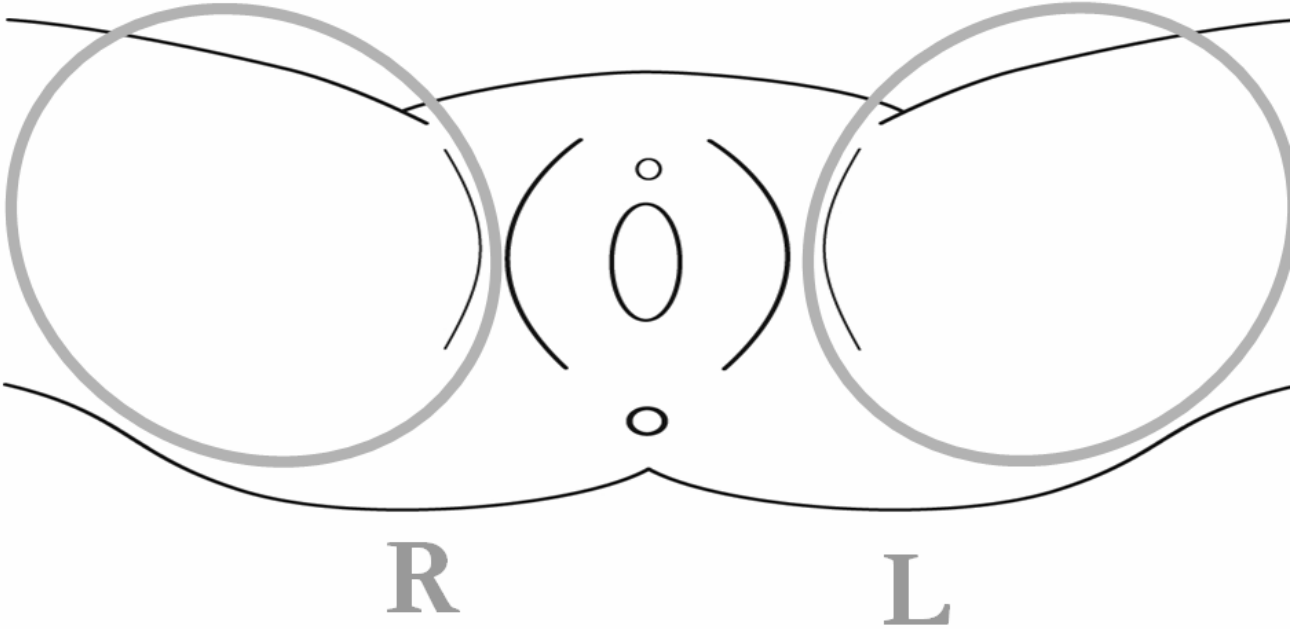
SURGERY FOR UI CODES	
20	Anterior repair, Kelly plication, suburethral plication
21	Collagen injection
22	Durasphere injection
23	Other periurethral bulking agent
24	Laparoscopic Burch colposuspension
25	Marshall-Marchetti-Krantz (MMK) bladder suspension
26	Needle suspensions: Raz, Pereyra, Gittes
27	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

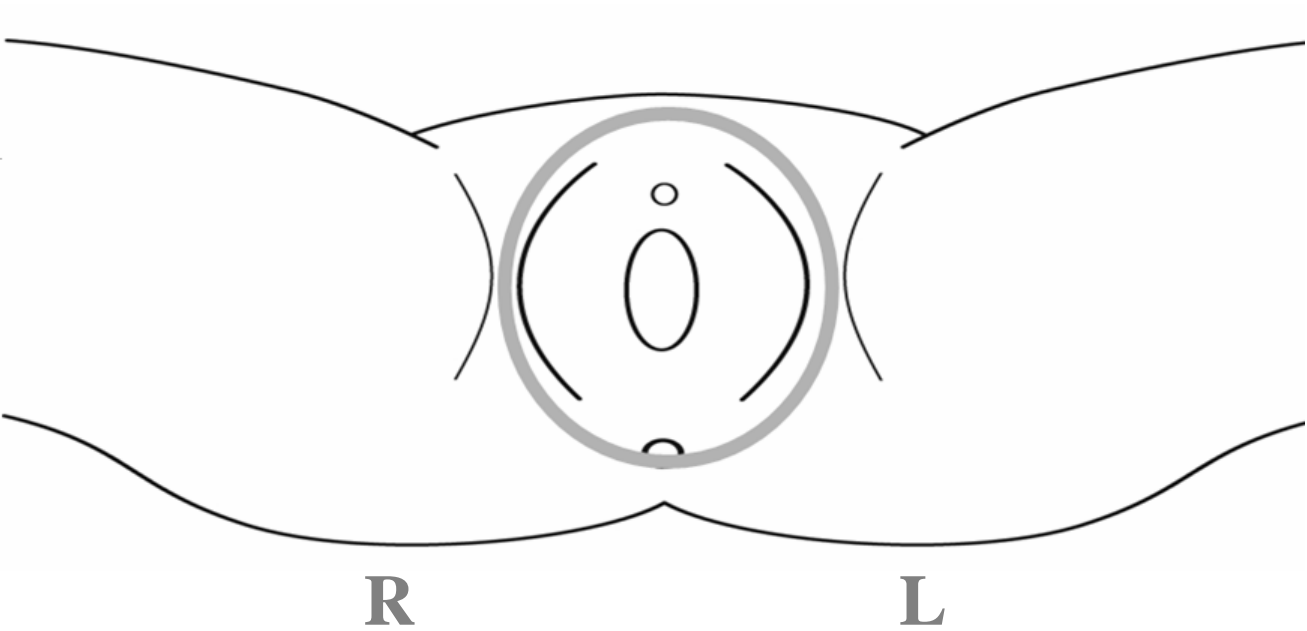
Body Map #1: Suprapubic



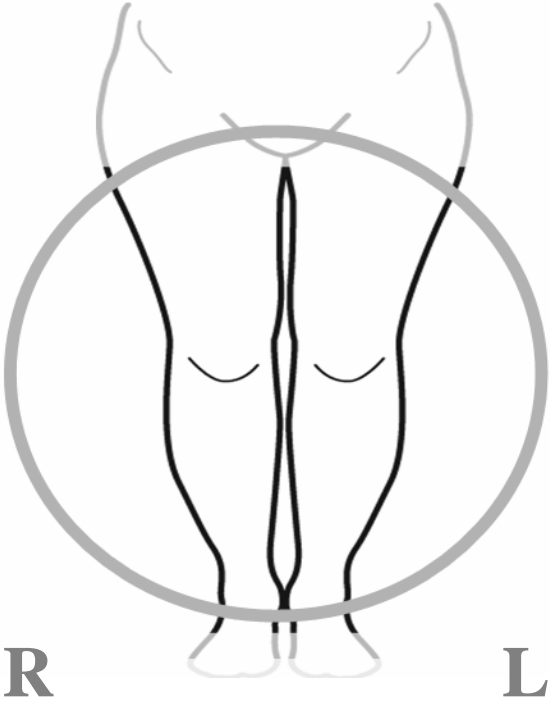
Body Map #2: Groin



Body Map #4: Vulva



Body Map #6: Upper & Lower Legs



Body Map #6: UPPER & LOWER LEGS

