

SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY:

A1. STUDY ID #:	<input type="text" value="LABEL"/>	A2. VISIT # F/U 2 Weeks TF2W
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: BLADDER AND BOWEL SYMPTOMS

B1. Compared to before your surgery for urinary incontinence, have you had an increase in your frequency of urination?

- YES 1
- NO 2

B2. 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

B2h. If yes, describe: _____

B3. 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

B4. 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

B3g. If yes, describe: _____

B5. Do you currently experience a feeling of incomplete bladder emptying?

- YES 1
- NO 2

B6. 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

B7. 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 B8

B7a. 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

B8. Do you have leaking or loss of control of gas? YES..... 1
NO 2 → **SKIP TO B9**

B8a. 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

B9. Do you have leaking or loss of control of liquid stool? YES..... 1
NO 2 → **SKIP TO B10**

B9a. 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

B10. Do you have leaking or loss of control of solid stool? YES 1
NO 2 → **SKIP TO SECTION C**

B10a. 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
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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

E1. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **PHYSICIAN VISITS** SINCE SURGERY? ASK,

Have you seen a doctor (nurse practitioner, physician's assistant) for any reason since your surgery?

YES 1

NO 2 → **SKIP TO E3**

E2. DATES OF AND REASONS FOR ANY **PHYSICIAN VISITS**; ASK,

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

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

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

E3. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY **EMERGENCY ROOM VISITS** SINCE HER SURGERY? ASK,

Have you been to an emergency room for any reason since your surgery?

YES 1

NO 2 → **SKIP TO E5**

E4. 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 surgery?

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

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

E5. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY NEW ABDOMINAL OR PELVIC SURGERY SINCE HER UITN SURGERY? ASK,

Have you had any new abdominal or pelvic surgery since your surgery?

YES 1

NO 2 → SKIP TO E7

E6. 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. ↓

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

E7. OTHER THAN ANY DESCRIBED ABOVE IN E6, DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY HOSPITAL ADMISSIONS SINCE HER SURGERY? ASK,

Have you been hospitalized for any (other) reason since your surgery?

YES 1

NO 2 → SKIP TO E9

E8. DATES OF AND REASONS FOR HOSPITAL ADMISSIONS. ASK,

What was (were) the (approximate) date(s) and reason for each hospitalization that occurred since your surgery?

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

	a.	b.	c.
	APPROXIMATE DATE	REASON FOR HOSPITALIZATION	SOURCE CODE
1	___ / ___ / _____	_____	_____
2	___ / ___ / _____	_____	_____
3	___ / ___ / _____	_____	_____

E9. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY ANTIBIOTICS PRESCRIBED SINCE DISCHARGE?

Since your surgery, has a doctor prescribed any antibiotics?

YES 1

NO 2 ➔ **SKIP TO E11**

E10. RECORD EACH ANTIBIOTIC BY NAME

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

	a.	b.	c.	d.	e.
	ANTIBIOTIC NAME (PRINT NAME PRECISELY)	NUMBER OF DAYS TAKEN	IS THE PATIENT STILL TAKING THIS MEDICATION?	REASON PRESCRIBED	SOURCE CODE†
1		____	YES1 NO..... 2		____
2		____	YES1 NO..... 2		____
3		____	YES1 NO..... 2		____

E11. DOES THE PATIENT REPORT OR IS THERE EVIDENCE OF ANY MEDICATION PRESCRIBED FOR THE TREATMENT OF LOWER URINARY TRACT SYMPTOMS SINCE DISCHARGE? ASK,

Since your surgery, has a doctor prescribed any medication for the treatment of lower urinary tract symptoms?

YES 1

NO 2 ➔ **SKIP TO F1**

E12. RECORD EACH MEDICATION BY NAME

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

	a.	b.	c.	d.	e.
	MEDICATION NAME (PRINT NAME PRECISELY)	NUMBER OF DAYS TAKEN	IS THE PATIENT STILL TAKING THIS MEDICATION?	REASON PRESCRIBED	SOURCE CODE†
1		____	YES1 NO..... 2		____
2		____	YES1 NO..... 2		____
3		____	YES1 NO..... 2		____

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: _____



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

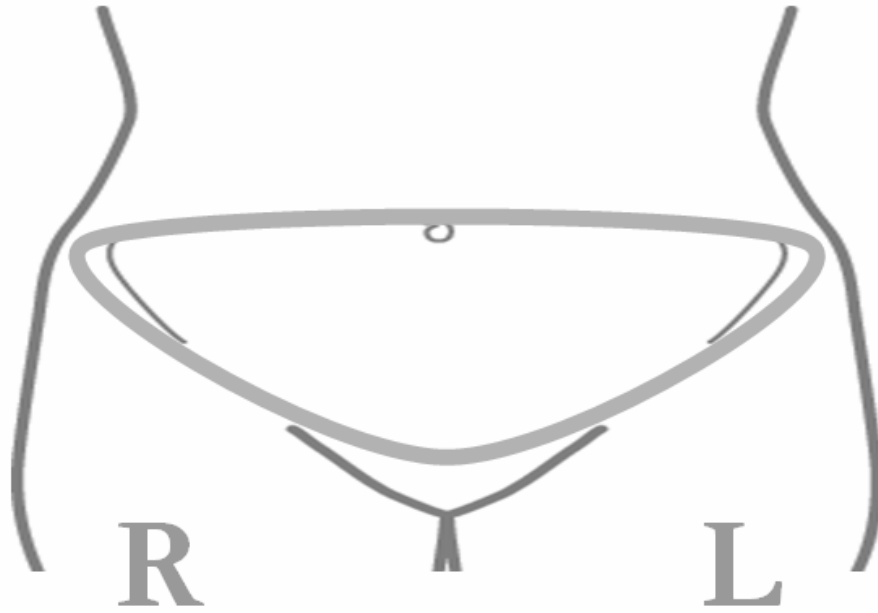
SLING REVISION CODES	
60	Tape loosening
61	Tape incision

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

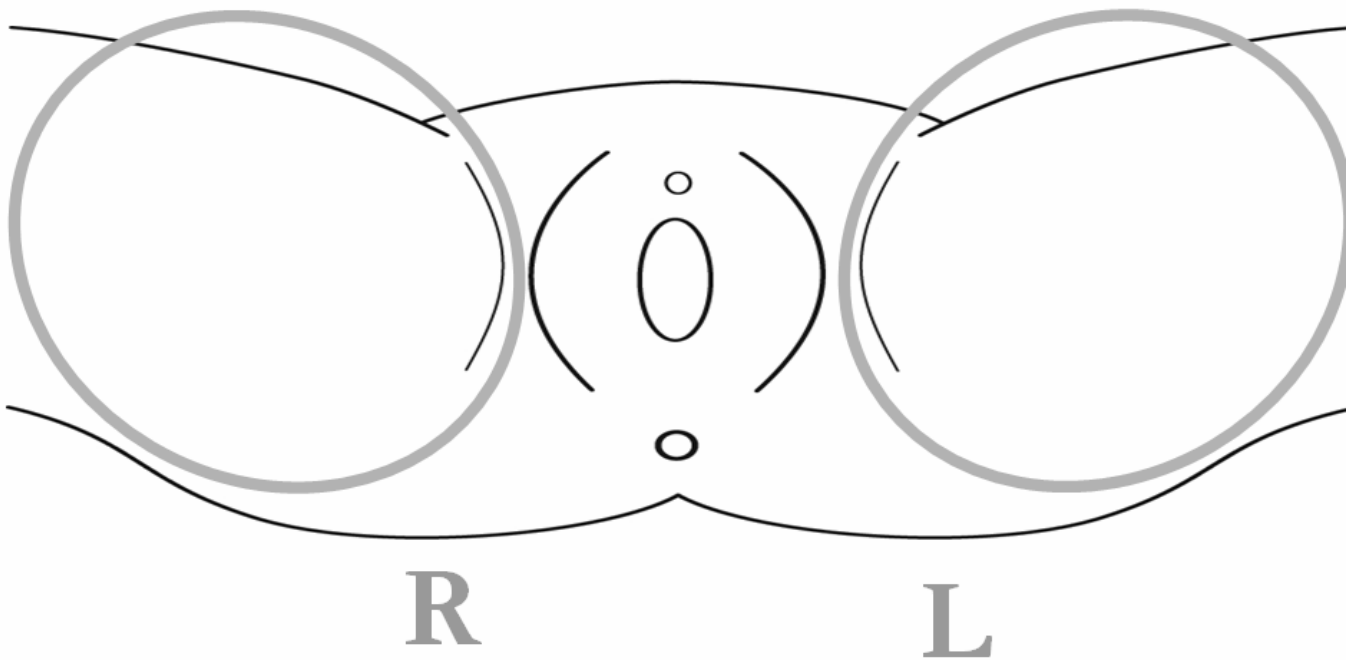
TREATMENT CODES	
40	Medicine (drug treatment)
41	Bladder training (including behavior changes involving the timing of urination or changes in fluid intake)
42	Pelvic muscle exercises (Kegel exercises)
43	Electrical stimulation
44	Electromagnetic therapy
45	Biofeedback
46	Acupuncture or other alternative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



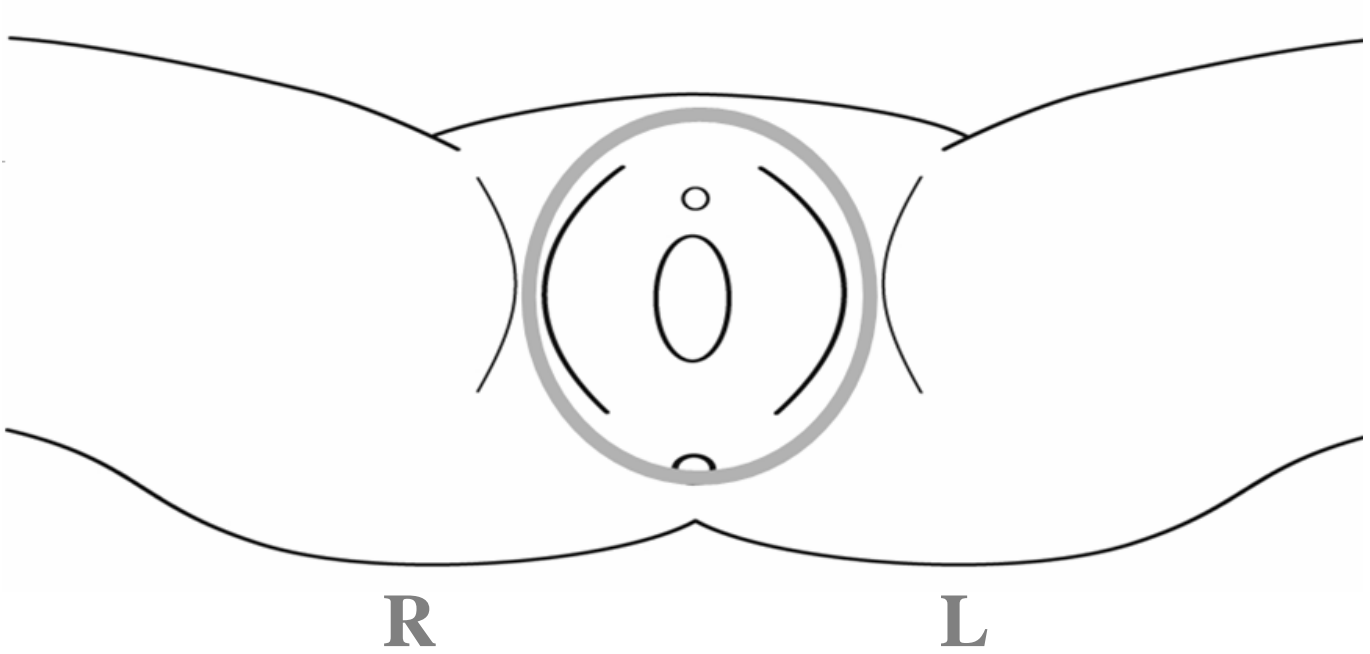
Body Map #1: Suprapubic



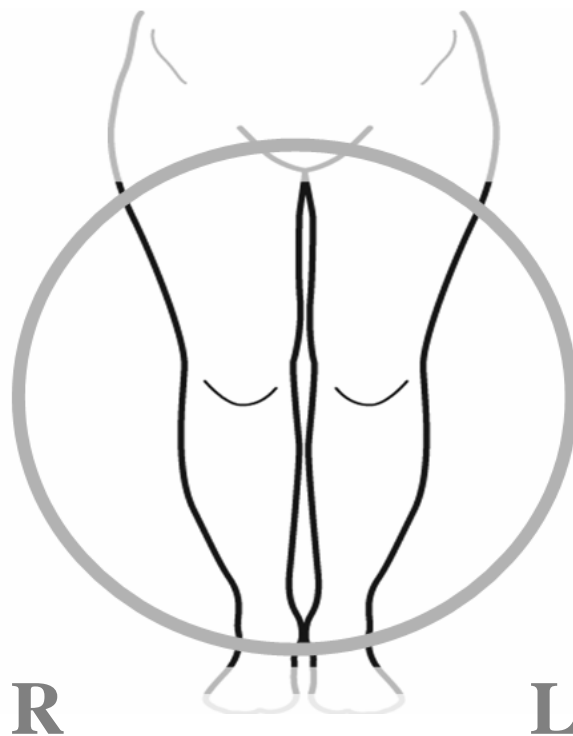
Body Map #2: Groin



Body Map #4: Vulva



Body Map #6: Upper & Lower Legs





Body Map #6: UPPER & LOWER LEGS

