PFDN **OPUS** Form 00C CONTACT

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___

COORDINATOR TO COMPLETE WITH SUBJECT:

A2. Interview language preference 1.☐ English 2.☐ Spanish

SECTION B: PATIENT IDENTIFYING INFORMATION

B1. Patient's Name: _____ (a) First _____ (b) Middle Initial _____ (c) Last

d. Preferred Title? 1.☐ Mrs. 2.☐ Miss 3.☐ Ms. 4.☐ Dr. 5.☐ Rev. 6.☐ Other:_____

e. Preferred Name? _____

B2. Address: _____ (a) Street Number _____ (b) Street Name _____ (c) St./Rd./Dr.

_____ (d) Apartment Number _____ (e) Rural Route Number

B3. City: _____ B4. State: ___ ___ B5. Zip: ___ ___ ___ ___ ___

B6. 1st Phone: (____) ____ - _____ a. Where? 1.☐ Home 2.☐ Cell 3.☐ Work b. Best Time ____ c. 1.☐ AM 2.☐ PM

B7. 2nd Phone: (____) ____ - _____ a. Where? 1.☐ Home 2.☐ Cell 3.☐ Work b. Best Time ____ c. 1.☐ AM 2.☐ PM

B8. 3rd Phone: (____) ____ - _____ a. Where? 1.☐ Home 2.☐ Cell 3.☐ Work b. Best Time ____ c. 1.☐ AM 2.☐ PM

SECTION C: ALTERNATE CONTACT INFORMATION

C1. Was a Contact Person identified? 1.☐ Yes 2.☐ No →END

C2. Contact's Name: _____ (a) First _____ (b) Middle Initial _____ (c)Last

C3. Relation to Patient: 1.☐ Spouse 2.☐ Daughter 3.☐ Son 4.☐ Mother 5.☐ Father 6.☐ Caregiver
7.☐ Other: _____

C4. 1st Phone: (____) ____ - _____ a. Where? 1.☐ Home 2.☐ Cell 3.☐ Work b. Best Time ____ c. 1.☐ AM 2.☐ PM

C5. 2nd Phone: (____) ____ - _____ a. Where? 1.☐ Home 2.☐ Cell 3.☐ Work b. Best Time ____ c. 1.☐ AM 2.☐ PM

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___

C6. Address: _____ _____ _____
(a) Street Number (b) Street Name (c) St./Rd./Dr.

_____ _____
(d) Apartment Number (e) Rural Route Number

C7. City: _____ C8. State: ___ ___ C9. Zip: ___ ___ ___ ___ ___

C10. Comments: _____

_____

_____

TEMPORARY STATUS DIARY FOR LOCAL USE ONLY/NOT FOR DATA ENTRY

DATE	DISPOSITION	NOTES

HOLD DISPOSITION CODES:
HOLD FOR CONSENT/CONSULTING W/ FAMILY.....1
TOO SICK/ACUTELY ILL.....2
TEMPORARY NURSING HOME OR REHAB.....3
OTHER (Specify): _____.....8

PFDN **OPUS** Form 00S Schedule

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___

SECTION B: TRACKING – TO BE COMPLETED BY COORDINATOR

B1. Please indicate the scheduled and actual dates for each visit:

	Visit	Scheduled date (MM/DD/YYYY)	Actual date (MM/DD/YYYY)	Required Forms	Optional Forms
a.	Consent	1.☐ English 2.☐ Spanish	___ ___ / ___ ___ / 20___ ___		
b.	Screening	1.☐ Conduct QOL in Spanish	___ ___ / ___ ___ / 20___ ___	01 03 04 05 06 07 18	13C 09A
c.	Baseline	___ ___ / ___ ___ / 20___ ___	___ ___ / ___ ___ / 20___ ___	08	
p.	RCT → PPT	New ID ___ ___ / N ___ ___ ___ ___	___ ___ / ___ ___ / 20___ ___ PPT Consent date	20A	
d.	Surgery	___ ___ / ___ ___ / 20___ ___	___ ___ / ___ ___ / 20___ ___	10C 10S	09A
e.	2 week call/visit	___ ___ / ___ ___ / 20___ ___	___ ___ / ___ ___ / 20___ ___	07 12 17	19 09A 13C
f.	4-6 week visit	___ ___ / ___ ___ / 20___ ___	___ ___ / ___ ___ / 20___ ___	07 11 12 17	19 09A 13C
g.	3 month visit	___ ___ / ___ ___ / 20___ ___	___ ___ / ___ ___ / 20___ ___	07 12 17 18	19 09A 13C
h.	6 month call/visit	___ ___ / ___ ___ / 20___ ___	___ ___ / ___ ___ / 20___ ___	07 12 17 18	19 09A 13C
i.	9 month call/visit	___ ___ / ___ ___ / 20___ ___	___ ___ / ___ ___ / 20___ ___	07 12 17 18	19 09A 13C
j.	12 month visit	___ ___ / ___ ___ / 20___ ___	___ ___ / ___ ___ / 20___ ___	07 12 17 18 20	19 09A 13C
k.	Add'l treatment visit		___ ___ / ___ ___ / 20___ ___	12	19 09A 13C
l.	Add'l treatment visit		___ ___ / ___ ___ / 20___ ___	12	19 09A 13C
m.	Ineligible/Screen failure		___ ___ / ___ ___ / 20___ ___	20	
n.	Withdraw from clinic visits prior to 12 month follow up		___ ___ / ___ ___ / 20___ ___	QOL continues? 1.☐ Yes 2.☐ No→ 20	
o.	Completed 12 month clinic and QOL visits		___ ___ / ___ ___ / 20___ ___	20	

SECTION C: TRACKING – TO BE COMPLETED BY QOL INTERVIEWING STAFF

C1. Please indicate the scheduled and actual dates for each interview:

	Visit	Scheduled date (MM/DD/YYYY)	Actual date (MM/DD/YYYY)	Interview Completed?	Optional Forms
		Conduct interview in Spanish ☐			
a.	Baseline	___ ___ / ___ ___ / 20___ ___	___ ___ / ___ ___ / 20___ ___	1.☐ Yes 2.☐ No	13Q
b.	3 month follow up	___ ___ / ___ ___ / 20___ ___	___ ___ / ___ ___ / 20___ ___	1.☐ Yes 2.☐ No	13Q
c.	6 month follow up	___ ___ / ___ ___ / 20___ ___	___ ___ / ___ ___ / 20___ ___	1.☐ Yes 2.☐ No	13Q
d.	12 month follow up	___ ___ / ___ ___ / 20___ ___	___ ___ / ___ ___ / 20___ ___	1.☐ Yes 2.☐ No	13Q
e.	Withdraw from QOL prior to 12 month interview		___ ___ / ___ ___ / 20___ ___		

PFDN

OPUS

Form 01 ELIGIBILITY

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Initials:___ ___ ___ Online Entry ☐ DCC ☐

SECTION B: INCLUSION CRITERIA All answers MUST be YES

B1. Subject has signed informed consent……1.☐ Yes 2.☐ No

B2. Subject has Stage II, III or IV anterior vaginal prolapse (defined as POPQ Point Aa at -1, 0, +1, +2, or +3 cm).1.☐ Yes 2.☐ No

B3. Subject's surgical plan includes a vaginal approach for apical or anterior prolapse repair or colpocleisis……1.☐ Yes 2.☐ No

B4. The subject's answer to PFDI Question 4 – "Do you usually have a sensation of bulging or protrusion from the vaginal area?" was 1.☐ Yes 2.☐ No

B5. The subject's answer to PFDI Question 5 – "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?" was 1.☐ Yes 2.☐ No

B6. Is the answer YES to either B4 or B5 or both? ……1.☐ Yes 2.☐ No

B7. Subject is able to complete all study related items and interviews……1.☐ Yes 2.☐ No

B8. Subject is planning to be available to complete study follow-up for the next year……1.☐ Yes 2.☐ No

SECTION C: EXCLUSION CRITERIA (C3-C5 and C13 may be left blank) All answers MUST be NO

C1. Subject currently pregnant or planning pregnancy in the first post-operative year……1.☐ Yes 2.☐ No

C2. Subject has a contra-indication for a TVT……1.☐ Yes 2.☐ No

C3. Subject has/had a urethral diverticulum, current or previous ……1.☐ Yes 2.☐ No

C4. Subject has a history of femoral bypass ……1.☐ Yes 2.☐ No

C5. Subject is on current chemotherapy or has current or history of pelvic radiation……1.☐ Yes 2.☐ No

C6. Subject has had a TVT/TOT or other mid urethral sling procedure……1.☐ Yes 2.☐ No

C7. Subject currently participating in another interventional study for urinary incontinence……1.☐ Yes 2.☐ No

C8. Subject is currently receiving treatment of stress urinary incontinence (as defined in MOO)……1.☐ Yes 2.☐ No
[e.g., pessary/incontinence ring, supervised pelvic floor muscle exercise or medication (duloxetine or imipramine and alpha agonists. Current use of vaginal or systemic (oral, skin patch, ring, etc.) estrogen Is not an exclusion criterion unless used as treatment for incontinence.]

C9. Subject has an untreated urinary tract infection……1.☐ Yes 2.☐ No

C10. The subject's answer to PFDI Question 20 "Do you usually experience urine leakage related to coughing, sneezing or laughing?" was……1.☐ Yes 2.☐ No

C11. The subject's answer to PFDI Question 21 "Do you usually experience urine leakage related to physical exercise such as walking, running, aerobics, or tennis?" was……1.☐ Yes 2.☐ No

C12. The subject's answer to PFDI Question 22 "Do you usually experience urine leakage related to lifting or bending over?" was……1.☐ Yes 2.☐ No

C13. History of 2 or more inpatient hospitalizations for medical comorbidities in the previous 12 months……1.☐ Yes 2.☐ No

C14. Subject's life expectancy is less than one year due to other health conditions……1.☐ Yes 2.☐ No

SECTION D: ELIGIBILITY status

D1. Subject consented to 1.☐ RCT 2.☐ PPT Date of consent: ___ ___ /___ ___ / 20 ___ ___

D2. Eligibility status: 1.☐ Eligible, will participate 2.☐ Eligible, does not wish to participate 3.☐ Ineligible

D3. Was an exception requested? 1.☐ Yes 2.☐ No → END

D4. Exception was 1.☐ Approved Date: ___ ___ /___ ___ / 20 ___ ___ 2.☐ Not approved

Investigator Signature:_____ Date: ___ ___ / ___ ___ / 20 ___ ___

PFDN **OPUS** Form 03Q QOL DEMOGRAPHICS

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

DCC ☐

SECTION B: DEMOGRAPHICS AT BASELINE

B1. What is your current marital status? (choose only one)

1. ☐ Married 2. ☐ Living as married 3. ☐ Separated 4. ☐ Divorced 5. ☐ Widowed 6. ☐ Single, never married
7. ☐ Other_____

B2. What is the highest grade or year of school that you have completed?

1. ☐ Less than high school 2. ☐ Completed high school or equivalent 3. ☐ Some college/Associate degree
4. ☐ Completed 4 years of college 5. ☐ Graduate/Professional degree

B3. Next, we have some questions about employment during the past year, including self-employment. This does not include unpaid or volunteer work. Do you currently work?

1. ☐ Yes 2. ☐ No → Go to B4

a. What type of work do you currently do? [PROBE: What do you consider your occupation to be?]

Specify: _____

B4. Including yourself, how many people are currently living in your household? ___ ___

B5. Last year was your total family income before taxes $50,000 or more? 1. ☐ Yes 2. ☐ No → Go to b.

a. Was it $70,000 or more 1. ☐ Yes → Go to B6 2. ☐ No → Go to B6

b. Was it $30,000 or more 1. ☐ Yes → Go to B6 2. ☐ No

c. Was it $15,000 or more 1. ☐ Yes 2. ☐ No

If the subject is currently working:

B6. Is your annual income from your job $50,000 or more ? 1. ☐ Yes 2. ☐ No → Go to b.

a. Was it $70,000 or more 1. ☐ Yes → END 2. ☐ No → END

b. Was it $30,000 or more 1. ☐ Yes → END 2. ☐ No

c. Was it $15,000 or more 1. ☐ Yes

QOL Signature:_____ Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year)

PFDN **OPUS** Form 03 DEMOGRAPHICS

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

Online Entry ☐ DCC ☐

COORDINATOR TO COMPLETE WITH SUBJECT:

SECTION B: SOCIODEMOGRAPHIC INFORMATION

B1. What was your date of birth? ___ ___/___ ___/___ ___ ___ ___ (Month / Day / Year)

B2. Do you consider your ethnicity to be Hispanic or Latina?

1. ☐ Yes 2. ☐ No

B3. For this question on racial background, you may select one or more choices. Do you consider yourself to be...(check all that apply):

a. ☐ White/Caucasian

b. ☐ Black/African American

c. ☐ Asian

d. ☐ Native Hawaiian/Pacific Islander

e. ☐ American Indian/Alaskan Native

f. ☐ Other:_____

g. ☐ Refused

h. If more than one response for B3a-B3f is "Yes", then ask: "Which do you consider to be your primary racial background?" (choose only one)

1. ☐ White/Caucasian 2. ☐ Black/African American
3. ☐ Asian 4. ☐ Native Hawaiian/Pacific Islander
5. ☐ American Indian/Alaskan Native 6. ☐ Other

B4.What type of health insurance does the subject have (check all that apply)?

a. ☐ Private insurance (employment based or self-purchased) b. ☐ HMO
c. ☐ Medicaid d. ☐ Medicare
e. ☐ Self pay (without insurance) f. ☐ Other (Specify)_____
g. ☐ Don't know h. ☐ Refused

Investigator/ Coordinator Signature:_____ Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year)

PFDN

OPUS

Form 04 MEDICAL HISTORY

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

DCC ☐

COORDINATOR TO COMPLETE WITH SUBJECT:

SECTION B: TOBACCO USE

B1. Are you a current smoker? 1.☐ Yes 2.☐ No →Go to B2

a. On average, how many cigarettes per day do you now smoke? ___ ___ cigarettes/day

b. How many years have you smoked? ___ ___ years →Go to C1

B2. *(If not a current smoker)* Have you...

1.☐ Never smoked 2.☐ Quit smoking less than six months ago 3.☐ Quit smoking six or more months ago

SECTION C: OBSTETRICAL / MENSTRUAL STATUS

C1. Have you ever been pregnant? 1.☐ Yes 2.☐ No → Go to C2

a. How many Cesarean deliveries have you had? ___ ___

b. How many vaginal deliveries have you had (over 20 weeks)? ___ ___

C2. With regards to your menstrual cycle, are you currently... 1.☐ pre-menopausal 2.☐ post-menopausal 3.☐ not sure

C3. Are you currently using estrogen by prescription (excluding hormonal contraceptives)?

a.☐ oral b.☐ vaginal cream, tablets or cream c.☐ skin patch d.☐ No

SECTION D: SURGICAL HISTORY

D1. Have you ever had any surgery specifically for the treatment of stress urinary incontinence? 1.☐ Yes 2.☐ No → Go to D2

a. How many times have you undergone surgery specifically to treat your urinary incontinence (excluding urethral dilations/stretching of the urethra)? ___ ___

D2. Have you ever had any surgery specifically for the treatment of pelvic organ prolapse? 1.☐ Yes 2.☐ No →Go to D3

a. How many times have you undergone surgery specifically to treat your pelvic organ prolapse? ___ ___

D3. Have you had a hysterectomy? 1.☐ Yes 2.☐ No

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___

SECTION E: GENERAL MEDICAL HISTORY: OBTAIN BY SUBJECT REPORT OR MEDICAL RECORD REVIEW

E1. Have you had 3 or more urinary tract infections (bladder or kidney) that required treatment during the past year? 1.☐ Yes 2.☐ No

E2. Do you have diabetes? 1.☐ Yes 2.☐ No 55.☐ Don't know

a. If yes, what type(s) of treatment are you using to control your sugar (check all that apply)?

a.☐ Diet b.☐ Exercise c.☐ Oral Medication d.☐ Insulin e.☐ None

E3. Do you have connective tissue disease (such as, SLE, Marfans, Sjogrens, Scleroderma) 1.☐ Yes 2.☐ No 55.☐ Don't know

E4. For each system listed, indicate whether a condition is present or absent:

	1. Present	0. Absent
Cardiovascular-Respiratory System		
a. Cardiac (heart only)	1.	0.
b. Vascular (blood, blood vessels and cells, marrow, spleen, lymphatics)	1.	0.
c. Respiratory (lungs, bronchi, trachea below the larynx)	1.	0.
d. EENT (eye, ear, nose, throat, larynx)	1.	0.
Gastrointestinal System		
e. Upper GI (esophagus, stomach, duodenum, biliary and pancreatic tract)	1.	0.
f. Lower GI (intestines, hernias)	1.	0.
g. Hepatic (liver only)	1.	0.
Genitourinary System		
h. Renal (kidneys only)	1.	0.
i. Other GU (ureters, bladder, urethra, genitals)	1.	0.
Musculo-Skeletal-Integumentary System		
j. MSI (muscles, bone, skin)	1.	0.
Neuropsychiatric System		
k. Neurologic (brain, spinal cord, nerves)	1.	0.
l. Psychiatric (mental)	1.	0.
General System		
m. Endocrine-Metabolic (includes diffuse infections, poisonings)	1.	0.

Investigator/ Coordinator Signature:_____ Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

PFDN **OPUS** Form 05 PHYSICAL EXAMINATION

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

DCC ☐

SECTION B: ANTHROPOMETRIC MEASURES

88. ☐ Not done

B1. Height ___ ___ ___ . ___ → a. 1. ☐ Inches 2. ☐ Centimeters

B2. Weight ___ ___ ___ . ___ → a. 1. ☐ Pounds 2. ☐ Kilograms

SECTION C: Urine Testing

Have subject empty bladder and collect specimen for urine testing:

C1. Is the dipstick test suggestive of a UTI?

2. ☐ No

1. ☐ Yes → Obtain micro and culture; treat UTI

SECTION D: PVR and COUGH STRESS TEST

88. ☐ Not done

Within 15 minutes of voiding and with subject in the LITHOTOMY position, insert catheter and collect post void residual urine

D1. PVR volume ___ ___ ___ ___ mL If PVR >150 mL consult with investigator

Maintaining the subject in LITHOTOMY position; attach fluid filled syringe to catheter and fill bladder to 300mL or maximum bladder capacity, whichever is less. Then remove catheter

LITHOTOMY POSITION, PROLAPSE UNREDUCED:

ASK SUBJECT TO VALSALVA AND COUGH:

D2. Was there urine leakage with Valsalva? 1. ☐ Yes 2. ☐ No

D3. Was there urine leakage with cough? 1. ☐ Yes 2. ☐ No

LITHOTOMY POSITION, PROLAPSE REDUCED WITH SWAB(S):

D4. Prolapse reduced with swab 1. ☐ Yes 2. ☐ No → Specify method and reason: _____

ASK SUBJECT TO VALSALVA AND COUGH:

D5. Was there urine leakage with Valsalva? 1. ☐ Yes 2. ☐ No

D6. Was there urine leakage with cough? 1. ☐ Yes 2. ☐ No

D7. Was urine leakage observed at D2-D6? 1. ☐ Yes → Go to Section E 2. ☐ No

STANDING POSITION, PROLAPSE REDUCED WITH SWAB(S);

88. ☐ Not done

ASK SUBJECT TO VALSALVA AND COUGH

D8. Was there urine leakage with Valsalva? 1. ☐ Yes 2. ☐ No

D9. Was there urine leakage with cough? 1. ☐ Yes 2. ☐ No

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___

SECTION E: POPQ EXAM Perform all measurements with the subject in lithotomy position. 88.☐ Not done

Record measurements to the nearest half centimeter (i.e., 0.0 or 0.5). Use a minus sign (–) for answers less than zero.

	Point	[Description]	Record Value	Range	Check if NA
E1.	GH	Strain [genital hiatus (mid external urethral meatus to posterior midline hymen)].....	___ ___ . ___	No limit	77.☐
E2.	PB	Strain [perineal body (posterior margin of genital hiatus to midanal opening)].....	___ ___ . ___	No limit	77.☐
E3.	Aa	[anterior vagina 3 cm from external urethral meatus].....	___ ___ . ___	-3 to +3	77.☐
E4.	Ba	[most dependent part of anterior vagina].....	___ ___ . ___	-3 to +TVL	77.☐
E5.	C	[cervix or vaginal cuff].....	___ ___ . ___	±TVL	77.☐
E6.	D	[posterior fornix (check NA if no uterus)].....	___ ___ . ___	±TVL	77.☐
E7.	Ap	[posterior vagina 3 cm from hymen].....	___ ___ . ___	-3 to +3	77.☐
E8.	Bp	[most dependent part of posterior vagina].....	___ ___ . ___	-3 to +TVL	77.☐
E9.	TVL	[total vaginal length].....	___ ___ . ___	No limit	77.☐

Investigator/ Coordinator Signature:_____ Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

A4. Visit: 1.☐ Baseline 2.☐ 2 wk 3.☐ 4-6 wk 4.☐ 3 mo 5.☐ 6 mo 6.☐ 9 mo 7.☐ 12 mo To DCC ☐

Date of last visit / call _____ (for site use only)

COORDINATOR TO COMPLETE WITH SUBJECT:

AT SCREENING/BASELINE

B1. Please tell me the names of any medications that are **prescribed** by any of your medical doctors, nurse practitioners (NP) or physician's assistants (PA).

PROBES: Think about any pills that you take by mouth, or liquids that you drink. Think about suppositories, vaginal creams, or skin patches.

Coordinator: Please list (print) all of the prescribed medications that the subject is currently taking.
If the medication is related to incontinence please list in Table 1, otherwise use Table 2.
On Table 2, assign sequence numbers for each medication starting from 51.
For all medications being used at the time of enrollment, enter the date of enrollment as the start date.

Were medications specified? 1.☐ Yes → **Enter Table 1 or Table 2** 2.☐ No

B2. Please tell me the names of any **pain** medications that you take regularly, either **prescribed or over-the-counter**.
Were medications specified? 1.☐ Yes → **Enter on Table 2** 2.☐ No

AFTER SURGERY

Coordinator: Please review the list of prescribed medications taken at previous study visits (as listed on Tables 1 and 2)
Only changes need to be entered in the tables.
If this is the final visit, please make sure to enter the End Date of the medication or check the Continuing box.

B3. Changes were made to the list: 1.☐ Yes 2.☐ No

B4. Since your last *visit/call* on *date*, have you taken any (other) **medications for incontinence** that were **prescribed** by any of your medical doctors, nurse practitioners (NP) or physician's assistants (PA)?
1.☐ Yes → **Enter on Table 1** 2.☐ No

B5. Since your last *visit/call* on *date*, have you taken any **medications for a urologic/gynecologic problem** that were **prescribed** by any of your medical doctors, nurse practitioners (NP) or physician's assistants (PA)? [This would include any medication the subject reports taking for a complication of the surgery]
1.☐ Yes → **Enter on Table 2** 2.☐ No

B6. Since your last *visit/call* on *date*, have you taken any **pain medications because of pain in the pelvic region**, whether prescribed or over-the-counter?
1.☐ Yes → **Enter on Table 2** 2.☐ No

- If there is an end in a medication, enter the end date. If the medication is restarted at a future date, make a new entry but use the same sequence number.
- When there is a new uro/gyn medication that is not already listed, assign it the next available sequence number and enter a start date. Please print the medication name.
- If the medication is related to urinary incontinence please list in Table 1, otherwise use Table 2.

Investigator/ Coordinator Signature: _____ Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year)

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___

A4. Visit: 1.☐ Baseline 2.☐2 wk 3.☐4-6 wk 4.☐3 mo 5.☐6 mo 6.☐9 mo 7.☐12 mo

TABLE 1: Medications for Urinary Incontinence

Coordinator: Table 1 is a cumulative record of medications. Check the Current Visit in item A4. If additional medications are necessary, use a second page with sequence #'s starting with 21.

***If this is the final visit, please complete either the End Date of the medication or check the Continuing box.*

Seq. No.	Name of Medication (print name precisely)	Start Date (MM/DD/YYYY)	End Date (MM/DD/YYYY)	Continuing on Final Visit? **
01	Duloxetine (Cymbalta)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
02	Imipramine	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
03	Tolterodine (Detrol LA)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
04	Tolterodine (Detrol)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
05	Oxybutynin (Ditropan)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
06	Oxybutynin (Ditropan XL)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
07	Oxybutynin (Oxytrol Patch)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
08	Solifenacin (Vesicare)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
09	Darifenacin (Enablex)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
10	Alpha agonists specify:_____	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
11	Hyoscyamine (e.g., Urised, Levsin)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
12	Trospium (Sanctura)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
13	Flavoxate (e.g., Urospas)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
14	Systemic estrogen (oral, skin patch, or non-vaginal topical, any type)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
15	Topical vaginal estrogen (cream, suppository, vaginal tablet or ring, any type)	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
__ __	Specify:_____	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
__ __	Specify:_____	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
__ __	Specify:_____	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
__ __	Specify:_____	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐
__ __	Specify:_____	__ __/ __ __/ 20 __ __	__ __/ __ __/ 20 __ __	☐

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___

A4. Visit: 1.☐ Baseline 2.☐ 2 wk 3.☐ 4-6 wk 4.☐ 3 mo 5.☐ 6 mo 6.☐ 9 mo 7.☐ 12 mo

TABLE 2: Other Prescription Medication and Non-Prescription Pain Medication

Coordinator: Table 2 is a cumulative record of medications. Check the Current Visit in item A4 and record medications starting with sequence # 51.

***If this is the final visit, please complete either the End Date of the medication or check the Continuing box.*

Seq. No.	Name of Medication (print name precisely)	Start Date (MM/DD/YYYY)	End Date (MM/DD/YYYY)	Continuing on Final Visit? **
51		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐
__ __		__ __/ __ __ / 20 __ __	__ __/ __ __ / 20 __ __	☐

PFDN

OPUS

Form 08 SURGICAL PLAN

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. ___ ___ / ___ ___ / 20 ___ ___ ___ A3. Initials: ___ ___ ___
Month Day Year

Online Entry ☐ DCC ☐

Note: B1 and B2 will be filled in automatically on the website

B1. Subject has signed informed consent 1.☐ Yes (autofill from Form 00 B1a) 2.☐ No →Subject ineligible for study

B2. Baseline quality of life interview completed 1.☐ Yes (autofill from Form 00 C1a) 2.☐ No →Subject ineligible for study

B3. Initials of the surgeon ___ ___ ___

B4. Surgical plan for vaginal prolapse repair:

1.☐ anterior repair only

2.☐ apical suspension only

3.☐ both anterior and apical

4.☐ colpocleisis with/ without any other procedure

B5. Expected date of surgery: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

If subject is in PPT:

B6. Is a TVT planned? 1.☐ Yes 2.☐ No →END

If subject is in RCT:

B7. Date of randomization: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

B8. Enter randomization number here:

___ ___ ___ ___ ___

Affix randomization label here

Investigator/ Coordinator Signature:_____ Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

PFDN # OPUS **Form 9A Adverse Event**

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

A4. AE # ___ ___ (event) 1. ☐ Initial Report 2. ☐ Update To DCC ☐

IF UROLOGIC/GYNECOLOGIC OR COMPLICATION OF SURGERY, ALSO INCLUDE ON FORM 17 OR 07, AS APPROPRIATE

B1. AE Diagnosis	.....
B1a. AE Description	....
B2. Specify Treatment	....

B3. Start Date	___ ___/___ ___/___ ___ ___ ___
B4. End Date (of outcome)	___ ___/___ ___/___ ___ ___ ___
B6. Causality Relationship to study treatment (TVT)	1. ☐ Likely 2. ☐ Unlikely 3. ☐ Not assessable
B7. Outcome *Specify the date above in "End Date."	1. ☐ Recovered/resolved* 2. ☐ Recovering/resolving 3. ☐ Not recovered/not resolved 4. ☐ Rec./resolved w. sequelae* 5. ☐ Fatal* 66. ☐ Unknown

B7a. Dindo score (see detailed definition): ___ ___ ___ (Roman no) ___ ___ ___ (suffix (if any)) ___ (d (if used)).

B8. Adverse Event Type: 1. ☐ SAE (Web-entry) → **Go to B9** 2. ☐ UAE 3. ☐ AE - DSMB report (Web-entry)

B9. Indication for reporting serious adverse event (SAE): An untoward medical occurrence that

1. ☐ resulted in death
2. ☐ is life threatening
3. ☐ requires inpatient hospitalization
4. ☐ results in persistent or significant disability or incapacity
5. ☐ is a congenital anomaly/birth defect
6. ☐ is another medically important condition

Web entry of this form immediately sends an email alert to the safety monitor, NIH project officer and DCC.
The safety monitor will contact the PI to complete SAE report.

Physician's Signature _____ Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year)

Dindo Scoring Table for Reference use only for B7a. Do not submit this page to DCC

Score	Grade		Definition
☐	I		Any deviation from the normal intraoperative or postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
	II		Requiring pharmacological treatment with drugs other than such allowed for grade I complications.
☐		IIa	Oral administration of drugs other than such allowed for grade I, excluding antibiotics
☐		IIabx	Oral administration of drugs other than such allowed for grade I, including antibiotics
☐		IIb	IV administration of drugs other than such allowed for grade I, including antibiotics; blood transfusions and total parenteral nutrition are also included
	III		Requiring surgical, endoscopic or radiological intervention
☐		IIIo	Additional surgical measures required during OPTIMAL Index procedure
☐		IIIa	Intervention not under general anesthesia
☐		IIIb	Intervention under general anesthesia
	IV		Life-threatening complication (including CNS complications)* requiring intermediate care or ICU management
☐		IVa	Single organ dysfunction (including dialysis)
☐		IVb	Multiorgan dysfunction
☐	V		Death of a patient
☐	Suffix "d"		If the patient suffers from a complication at the time of discharge, the suffix "d" (for "disability") is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

*Brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks.

PFDN

OPUS

Form 10C HOSPITALIZATION

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

DCC ☐

SECTION B: HOSPITALIZATION

B1. If inpatient: Admission: ___ ___ / ___ ___ (Month / Day) Discharge: ___ ___ / ___ ___ (Month / Day)

B2. If outpatient: Surgery: ___ ___ / ___ ___ (Month / Day)

B3. Blood transfusion after surgery 1.☐ Yes → Specify total # of units PRBC post-op: ___ ___ 2.☐ No

B4. Number of days subject was catheterized during hospital stay ___ ___ days

B5. Subject is voiding spontaneously at discharge 1.☐ Yes →Go to C1 2.☐ No

B6. Bladder drainage at time of discharge 1.☐ None 2.☐ Foley 3.☐ Suprapubic tube 4.☐ Intermittent self-catheterization

NOTE: If subject is catheterizing, call subject weekly and record on Form 15 Weekly Cath F/U.

SECTION C: PERI-OPERATIVE COMPLICATIONS

SURGEON TO COMPLETE THIS SECTION TO REPORT ANY AE/SAE DURING HOSPITALIZATION;
COMPLETE FORM 9A IF ITEM IS ASTERISKED

	Absent	Present	
C1.	☐		Wound complications
a.		☐	Superficial separation (suprapubic)
b.		☐	Superficial separation (vaginal)
c.		☐	Hematoma
d.		☐	Infection
e.		☐	Cellulitis (suprapubic)
f.		☐	Other*, specify:
C2.	☐		Febrile/dermatologic complication
a.		☐	Unexplained fever: ≥ 101 degrees
b.		☐	Urinary tract infection
c.		☐	Skin rash (excludes cellulitis)
d.		☐	Septic Shock/Bacteremia*
e.		☐	Allergic or anaphylactic reaction*
f.		☐	Other*, specify:
C3.	☐		Organ damage complications
a.		☐	Bladder or urethral injury
b.		☐	Intestinal/Rectal/Bowel injury*
c.		☐	Nerve injury
d.		☐	Other*, specify:
	Absent	Present	

C4.	☐		Cardiovascular complications
a.		☐	Superficial thrombophlebitis
b.		☐	Deep vein thrombosis*
c.		☐	Myocardial infarction*
d.		☐	Congestive heart failure*
e.		☐	Arrhythmia*
f.		☐	Severe hemorrhage (>1000cc/24 hr)*
g.		☐	Severe coagulopathy*
h.		☐	Other*, specify:
C5.	☐		Pulmonary complications
a.		☐	Pneumonia
b.		☐	Pulmonary embolus*
c.		☐	ARDS/Respiratory failure*
d.		☐	Other*, specify:
C6.	☐		GI complications:
a.		☐	SBO*
b.		☐	Ileus
d.		☐	Nausea and /or vomiting
c.		☐	Other*, specify:

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___

	Absent	Present	
C7.	☐		Neurologic complications
a.		☐	Altered limb or perineal sensation
b.		☐	Cerebral vascular accident*
c.		☐	Seizure
d.		☐	Neuropsychiatric disorder
e.		☐	Leg weakness
f.		☐	Other, specify*:

	Absent	Present	
C8.	☐		Other
a.		☐	Specify*:
b.		☐	Specify*:

C9. For any complication identified in C1-C8, that is not being reported on Form 09A, please report the treatment below. 77.☐ NA

	Item	Treatment
a.		
b.		
c.		

C10. Please provide a single Dindo Scoring for the most severe AE reported on this form. 77.☐ NA

Score	Grade		Definition
1. ☐	I		Any deviation from the normal intraoperative or postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
	II		Requiring pharmacological treatment with drugs other than such allowed for grade I complications.
2. ☐		IIa	Oral administration of drugs other than such allowed for grade I, excluding antibiotics
3. ☐		IIabx	Oral administration of drugs other than such allowed for grade I, including antibiotics
4. ☐		IIb	IV administration of drugs other than such allowed for grade I, including antibiotics; blood transfusions and total parenteral nutrition are also included
	III		Requiring surgical, endoscopic or radiological intervention
5. ☐		IIIo	Additional surgical measures required during OPUS Index procedure
6. ☐		IIIa	Intervention not under general anesthesia
7. ☐		IIIb	Intervention under general anesthesia
	IV		Life-threatening complication (including CNS complications)* requiring intermediate care or ICU management
8. ☐		IVa	Single organ dysfunction (including dialysis)
9. ☐		IVb	Multiorgan dysfunction
10. ☐	V		Death of a patient
11. ☐	Suffix "d"		If the patient suffers from a complication at the time of discharge, the suffix "d" (for "disability") is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

*Brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks.

Investigator/ Coordinator Signature:_____ Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

PFDN **OPUS** Form 10S SURGEON'S REPORT

A1. Site/Study ID #: ___ ___ / N ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Surgeon's Initials: ___ ___ ___

SECTION B: GENERAL

B1. Pre-operative prophylactic antibiotic	1. ☐ Yes 2. ☐ No
B2. Anesthesia	a. ☐ General b. ☐ Spinal c. ☐ Epidural d. ☐ Other, specify:_____
B3. Bladder drainage	1. ☐ Foley 2. ☐ Suprapubic 3. ☐ None
B4. Estimated blood loss	___ ___ ___ ___ cc
B5. PRBC transfusions:	1. ☐ Used → ___ ___ units PRBC 2. ☐ Not used
B6. DVT prophylaxis	1. ☐ Yes 2. ☐ No
B7. Operative time (from time of incision to time that dressing is placed)	___ ___ ___ minutes

SECTION C: PROCEDURES PLANNED/ PERFORMED

	Planned 1.Yes	Planned 2.No	Performed 1.Yes	Performed 2.No	If the answers to 'Planned' and 'Performed' do not agree, reason.
C1. TVT	1	2	1	2	
C2. Anterior repair	1	2	1	2	
C3. Apical suspension	1	2	1	2	
C4. Colpocleisis	1	2	1	2	

C5. Sham incision performed 77. NA

PROLAPSE REPAIR PROCEDURES BY VAGINAL APPROACH (CHECK ALL THAT APPLY)

C6. Anterior vaginal prolapse procedure(s)	C7. Posterior vaginal prolapse procedure(s)	C8. Apex	C9. Colpocleisis
a. ☐ paravaginal (attachment by suturing to arcus tendineus) b. ☐ colporrhaphy (plication of fibromusc. tissue) c. ☐ mesh augmentation d. ☐ other, specify: _____ e. ☐ none	a. ☐ midline plication of fibromusc. tissue (traditional colporrhaphy) b. ☐ defect directed repair c. ☐ perineorrhaphy d. ☐ levator plication e. ☐ mesh augmentation f. ☐ other, specify: _____ g. ☐ none	a. ☐ uterosacral ligament susp. b. ☐ sacrospinous ligament susp. c. ☐ McCall culdoplasty d. ☐ iliococcygeal repair e. ☐ pursestring repair of enterocele f. ☐ apical suspension kit g. ☐ other, specify: _____ h. ☐ none	a. ☐ total colpocleisis b. ☐ partial colpocleisis c. ☐ levator plication d. ☐ other, specify: _____ e. ☐ none

A1. Site/Study ID #: ___ ___ / N ___ ___ ___ ___

C10. Additional procedures (check all that apply) 1. ☐ None

a. ☐ Hysterectomy

b. ☐ Oophorectomy 1. ☐ Left 2. ☐ Right 3. ☐ Bilateral

c. ☐ Anal sphincter repair

d. ☐ Enterocele

e. ☐ Other, specify: _____

SECTION D: VAGINAL PROLAPSE PROCEDURES

		Anterior vagina	Posterior vagina	Apex
D1.	Suture material (check all that apply)	77. ☐ Not used or N/A	77. ☐ Not used or N/A	77. ☐ Not used or N/A
a.	Absorbable	1. ☐ Used	1. ☐ Used	1. ☐ Used
b.	Permanent monofilament	1. ☐ Used	1. ☐ Used	1. ☐ Used
c.	Permanent mulitfilament	1. ☐ Used	1. ☐ Used	1. ☐ Used
d.	Other	1. ☐ Used	1. ☐ Used	1. ☐ Used
D2.	Graft type (check all that apply)	77. ☐ Not used or N/A	77. ☐ Not used or N/A	77. ☐ Not used or N/A
a.	Polypropylene	☐ Used	☐ Used	☐ Used
b.	Expanded PTFE(Goretex)	☐ Used	☐ Used	☐ Used
c.	Polyethylene (Mersilene)	☐ Used	☐ Used	☐ Used
d.	Polyglactin (Vicryl)	☐ Used	☐ Used	☐ Used
e.	Porcine small intestine xenograft	☐ Used	☐ Used	☐ Used
f.	Bovine pericardium xenograft	☐ Used	☐ Used	☐ Used
g.	Dura Mater allograft	☐ Used	☐ Used	☐ Used
h.	Fascia Lata allograft	☐ Used	☐ Used	☐ Used
i.	Autologous Rectus Sheath fascia	☐ Used	☐ Used	☐ Used
j.	Autologous Fascia Lata	☐ Used	☐ Used	☐ Used
k.	Autologous vaginal tissue	☐ Used	☐ Used	☐ Used
l.	Other	☐ specify	☐ specify	☐ specify

A1. Site/Study ID #: ___ ___ / N ___ ___ ___ ___

		Anterior wall	Posterior wall	Apex
D3.	Trocar	77. ☐ Not used or N/A	77. ☐ Not used or N/A	77. ☐ Not used or N/A
a.	Kit name			
b.	Manufacturer			
c.	Material			
D4.	Non-Trocar	77. ☐ Not used or N/A	77. ☐ Not used or N/A	77. ☐ Not used or N/A
a.	Kit name			
b.	Manufacturer			
c.	Material			

SECTION E: INTRAOPERATIVE ADVERSE EVENTS

E1. Bladder perforation 1. ☐ Yes 2. ☐ No → Go to E2

a. number: ___ ___ describe: _____

b. ☐ during TVT

c. ☐ anterior repair

E2. Ureteral Injury 1. ☐ Yes 2. ☐ No → Go to E3

a. approach used to treat the ureteral injury 1. ☐ vaginal 2. ☐ laparoscopic* 3. ☐ laparotomy*

b. ☐ suture removed to treat the ureteral injury

c. ☐ stent placed to treat the ureteral injury

E3. Were there any other adverse events 1. ☐ Yes (check all that apply) 2. ☐ No → End

E4. ☐ Urethral injury

E5. ☐ Rectal Injury* Treatment approach: 1. ☐ vaginal 2. ☐ laparoscopic 3. ☐ laparotomy

E6. ☐ Other bowel injury* Treatment approach: 1. ☐ vaginal 2. ☐ laparoscopic 3. ☐ laparotomy

E7. ☐ Major vascular injury*

E8. ☐ Anesthesia related complications

E9. ☐ Other (Specify)_____

* Indicates need to complete SAE Form 09A

A1. Site/Study ID #: ___ ___ / N ___ ___ ___ ___

E10. Please provide a single Dindo Scoring for the most severe AE reported on this form. 77.☐ NA

Score	Grade		Definition
☐	I		Any deviation from the normal intraoperative or postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions[1] Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
	II		Requiring pharmacological treatment with drugs other than such allowed for grade I complications.
☐		IIa	Oral administration of drugs other than such allowed for grade I, excluding antibiotics
☐		IIabx	Oral administration of drugs other than such allowed for grade I, including antibiotics
☐		IIb	IV administration of drugs other than such allowed for grade I, including antibiotics; blood transfusions and total parenteral nutrition are also included
	III		Requiring surgical, endoscopic or radiological intervention
☐		IIIo	Additional surgical measures required during OPUS Index procedure[2]
☐		IIIa	Intervention not under general anesthesia
☐		IIIb	Intervention under general anesthesia
	IV		Life-threatening complication (including CNS complications)[3] requiring intermediate care or ICU management
☐		IVa	Single organ dysfunction (including dialysis)
☐		IVb	Multiorgan dysfunction
☐	V		Death of a patient
☐	Suffix "d"		If the patient suffers from a complication at the time of discharge, the suffix "d" (for "disability") is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

[1] Grade 1 also includes bladder perforation during TVT that only requires removal and replacement of the trocar or a suture removal from around a ureter

[2] Grade IIIo also includes ureteral stent that was left in at the end of the operative case or a formal ureteral repair

[3] Grade IV also includes brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excludes transient ischemic attacks.

Investigator Signature:_____ Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

ENCLOSE FORM IN ENVELOPE PROVIDED, AND MAIL TO DCC.

PFDN

OPUS

Form 11 Post Operative Visit

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

DCC ☐

Complete this form in addition to Form 12 at the 4-6 Week Visit

SECTION B: COMPLICATIONS

Indicate if any of the following complications have become apparent since discharge from the hospital or your last contact with the subject. Items marked with an asterisk (*) REQUIRE that the adverse events form 09A also be completed.

	Absent	Present	
B1.	☐		Wound complications
a.		☐	Mesh Infection/erosion/ rejection/fistula*
b.		☐	TVT Infection/erosion/rejection/fistula*
c.		☐	Superficial separation
d.		☐	Fascial separation/Dehiscence*
e.		☐	Hematoma
f.		☐	Infection
g.		☐	Hernia
h.		☐	Cellulitis
i.		☐	Other*, specify:
B2.	☐		Febrile/dermatologic complication
a.		☐	Unexplained fever ≥ 101 degrees
b.		☐	Pelvic abscess*
c.		☐	Septic Shock/Bacteremia*
d.		☐	Allergic or anaphylactic reaction*
e.		☐	Urinary tract infection
f.		☐	Skin rash (excludes cellulitis)
g.		☐	Other*, specify:
B3.	☐		Organ damage complications
a.		☐	Bladder or urethral injury*
b.		☐	Fistula*
c.		☐	Intestinal/Rectal/Bowel injury*
d.		☐	Vascular*
e.		☐	Nerve injury*
f.		☐	Other*, specify:

	Absent	Present	
B4.	☐		Cardiovascular complications
a.		☐	Deep vein thrombosis*
b.		☐	Myocardial infarction*
c.		☐	Congestive heart failure*
d.		☐	Arrhythmia*
e.		☐	Severe hemorrhage (>1000cc/24 hr)*
f.		☐	Severe coagulopathy*
g.		☐	Superficial thrombophlebitis
h.		☐	Other*, specify:
B5.	☐		Pulmonary complications
a.		☐	Pulmonary edema/CHF*
b.		☐	Pneumonia*
c.		☐	Pulmonary embolus*
d.		☐	ARDS/Respiratory failure*
e.		☐	Atelectasis
f.		☐	Other*, specify:
B6.	☐		GI complications:
a.		☐	Hepatitis/jaundice/liver failure*
b.		☐	GI bleed*
c.		☐	Ileus/SBO*
d.		☐	Nausea/emesis/bloating
e.		☐	Other*, specify:

PFDN **OPUS** Form 11 Post Operative Visit

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

DCC ☐

	Absent	Present	
B7.	☐		Neurologic complications
a.		☐	Cerebral vascular accident*
b.		☐	Seizure*
c.		☐	Neuropsychiatric disorder*
d.		☐	Altered limb or perineal sensation
e.		☐	Leg weakness*
f.		☐	Other*, specify:

	Absent	Present	
B8.	☐		Other
a.		☐	Specify:
b.		☐	Specify:
c.		☐	Specify:

B9. For any complication identified in B1-B8 that is not being reported on Form 09A, please report the treatment below. 77.☐ NA

	Item	Treatment
a.		
b.		
c.		

B10. Please provide a single Dindo Scoring for the most severe AE reported on this form. 77.☐ NA

Score	Grade		Definition
☐	I		Any deviation from the normal intraoperative or postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
	II		Requiring pharmacological treatment with drugs other than such allowed for grade I complications.
☐		IIa	Oral administration of drugs other than such allowed for grade I, excluding antibiotics
☐		IIabx	Oral administration of drugs other than such allowed for grade I, including antibiotics
☐		IIb	IV administration of drugs other than such allowed for grade I, including antibiotics; blood transfusions and total parenteral nutrition are also included
	III		Requiring surgical, endoscopic or radiological intervention
☐		IIIo	Additional surgical measures required during OPUS Index procedure
☐		IIIa	Intervention not under general anesthesia
☐		IIIb	Intervention under general anesthesia
	IV		Life-threatening complication (including CNS complications)* requiring intermediate care or ICU management
☐		IVa	Single organ dysfunction (including dialysis)
☐		IVb	Multiorgan dysfunction
☐	V		Death of a patient
☐	Suffix "d"		If the patient suffers from a complication at the time of discharge, the suffix "d" (for "disability") is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

*Brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks.

Investigator/ Coordinator Signature: _____ Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year)

PFDN

OPUS

Form 12 FOLLOW UP VISIT

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

A4. Visit: 1. ☐ 2 wk 2. ☐ 4-6 wk 3. ☐ 3 mo 4. ☐ 6 mo 5. ☐ 9 mo 6. ☐ 12 mo 7. ☐ other DCC ☐

Date of last visit / call : _____ (for coordinator's use only)

Section B: Follow up evaluations and Forms use

B1.	Method of Contact		Interval	Procedures	Form Completion Required				
	Visit	Phone			07	11	12	17	18
a.	☐	☐	2wk		Yes	No	Yes	Yes	No
b.	☐	☐	4-6 wk*	Required: PVR, Urinalysis	Yes	Yes	Yes	Yes	No
c.	☐	☐	3 mo*	Required: PVR, Urinalysis, POPQ, CST	Yes	No	Yes	Yes	Yes
d.	☐	☐	6 mo		Yes	No	Yes	Yes	Yes
e.	☐	☐	9 mo		Yes	No	Yes	Yes	Yes
f.	☐	☐	12 mo*	Required: PVR, Urinalysis, POPQ,CST	Yes	No	Yes	Yes	Yes
g.	☐	☐	other	Addtional procedures or visits	PRN	No	Yes	PRN	No

* If an in-person clinic visit did not occur at these intervals, complete a Protocol Deviation Form 13C
Contact at 2wk, 6 mo and 9 mo may occur by phone or by in-person visit, if clinically indicated

Section C: Retreatment and complications screen

C1. Have you been treated for urinary incontinence since your last *visit/call* on *date*? 1. ☐ Yes 2. ☐ No → Go to C3

C2. What was the treatment?

Check If yes	Treatment	Start Date (mm/dd/yyyy)	Specify	Record On Form
a. ☐	Surgery	/ /20		17
b. ☐	Medication	/ /20		07
c. ☐	Pessary for incontinence	/ /20		17
d. ☐	Supervised Pelvic Muscle Exercises	/ /20	# of sessions __ __	17
e. ☐	Time Voiding & Fluid Management	/ /20	# of sessions __ __	17
f. ☐	Periurethral injection	/ /20		17
g. ☐	Botox injection	/ /20		17
h. ☐	E-stim	/ /20		17
i. ☐	Other treatment for incontinence, specify _____	/ /20		17 or 07

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

C3. Are you voiding spontaneously? 1. ☐ Yes 2. ☐ No

C4. Since your last *visit/call* on *date*, have you used a catheter to empty your bladder? 1. ☐ Yes 2. ☐ No → Go to C5

a. When did you start using a catheter? ___ ___/___ ___
Month Day

b. Are you still using a catheter 1. ☐ Yes → Go to C5 2. ☐ No

c. When did you stop using a catheter? ___ ___/___ ___
Month Day

NOTE: IF SUBJECT IS NOT VOIDING AND NOT USING A CATHETER, INFORM INVESTIGATOR
IF CATHETER IN USE, FOLLOW WEEKLY WITH FORM 15 CATH F/U

C5. Since your last *visit/call* on *date*, have you been treated for a urinary tract infection? 1. ☐ Yes 2. ☐ No → Go to Section D

a. (If yes) Were you prescribed antibiotics for the urinary tract infection? 1. ☐ Yes 2. ☐ No

IF THIS IS A PHONE FOLLOW-UP, COMPLETION OF SECTIONS D-F IS NOT REQUIRED → END.

SECTION D: Urine Testing

88. ☐ Not done

Have subject empty bladder and collect specimen for urine testing:

D1. Dipstick test suggestive of a UTI? 2. ☐ No

1. ☐ Yes → Obtain urine for micro & culture. Record only additional urine test results on Form 19.
Continue with PVR and CST

SECTION E: PVR and COUGH STRESS TEST

88. ☐ Not done

Within 15 minutes of voiding and with subject in the LITHOTOMY position, insert catheter and collect post void residual urine

E1. PVR volume ___ ___ ___ ___ mL If PVR >150 mL consult with investigator,

a. Was ISC recommended? 2. ☐ No 1. ☐ Yes→ Follow weekly with Form 15 Cath F/U

E2. Is this the 3 month or 12 month visit? 2. ☐ No → END

1. ☐ Yes → Continue with CST and/or POPQ

Maintaining the subject in LITHOTOMY position; attach fluid filled syringe to catheter and fill bladder to 300mL or maximum bladder capacity, whichever is less, then remove catheter

LITHOTOMY POSITION

ASK SUBJECT TO VALSALVA AND COUGH:

E3. Was there urine leakage with Valsalva? 1. ☐ Yes 2. ☐ No

E4. Was there urine leakage with cough? 1. ☐ Yes 2. ☐ No

E5. Was urine leakage observed at E2-E3? 1. ☐ Yes → Go to Section F 2. ☐ No

STANDING POSITION

88. ☐ Not done

ASK SUBJECT TO VALSALVA AND COUGH

E6. Was there urine leakage with Valsalva? 1. ☐ Yes → Go to Section F 2. ☐ No

E7. Was there urine leakage with cough? 1. ☐ Yes 2. ☐ No

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

SECTION F: POPQ EXAM 88. ☐ Not done
Perform all measurements in lithotomy position. Please use a minus (–) for answers less than zero.

	Point	[Description]	Record Value	Range	Check if NA
F1.	GH	Strain [genital hiatus (mid external urethral meatus to posterior midline hymen)].....	___ ___ . ___	No limit	☐
F2.	PB	Strain [perineal body (posterior margin of genital hiatus to midanal opening)].....	___ ___ . ___	No limit	☐
F3.	Aa	[anterior vagina 3 cm from external urethral meatus].....	___ ___ . ___	-3 to +3	☐
F4.	Ba	[most dependent part of anterior vagina].....	___ ___ . ___	-3 to +TVL	☐
F5.	C	[cervix or vaginal cuff].....	___ ___ . ___	±TVL	☐
F6.	D	[posterior fornix (check NA if no uterus)].....	___ ___ . ___	±TVL	☐
F7.	Ap	[posterior vagina 3 cm from hymen].....	___ ___ . ___	-3 to +3	☐
F8.	Bp	[most dependent part of posterior vagina].....	___ ___ . ___	-3 to +TVL	☐
F9.	TVL	[total vaginal length].....	___ ___ . ___	No limit	☐

Investigator/ Coordinator Signature:_____ Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

PFDN

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Form 13C Protocol Deviation

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

A4. Visit: 1. ☐ Baseline 2. ☐ 2 wk 3. ☐ 4-6 wk 4. ☐ 3 mo 5. ☐ 6 mo 6. ☐ 9 mo 7. ☐ 12 mo To DCC ☐

SECTION B: Visit deviations

B1. 1. ☐ Visit missed Reason: _____

SECTION C: Other Deviation that affected the following

	Form	Section and/or Item #'s	Deviation	Reason
C1.				
C2.				
C3.				
C4.				
C5.				

Investigator/ Coordinator Signature: _____ Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year)

PFDN

OPUS

Form 13Q QOL Protocol Deviation

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

A4. Visit: 1. ☐ Baseline 2. ☐ 3 mo 3. ☐ 6 mo 4. ☐ 12 mo To DCC ☐

B: Protocol Deviation related to Quality of Life Measures Completion

B1. QOL Measures: 1. ☐ Not Done 2. ☐ Partially completed 3. ☐ Other, specify: _____

B2. If partially completed, check the measures not completed:

Measure
a. ☐ SF-36
b. ☐ EQ-5D
c. ☐ Physical Activity
d. ☐ PGII (after surgery only)
e. ☐ Hunskaar
f. ☐ PFDI
g. ☐ PFIQ
h. ☐ Pain Scale
i. ☐ PISQ
j. ☐ Adaptation
k. ☐ Expectations Measure (at baseline only) (currently not implemented)
l. ☐ Demographics (at baseline only)

B3. Reason _____

_____

QOL Signature: _____ Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year)

PFDN **OPUS** Form 13U Unmasking Report

A1. Site/Study ID #: ___ ___ / R ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Site Initials: ___ ___ ___

Online Entry ☐ DCC ☐

SECTION B: UNMASKING

B1. Date unmasking occurred: ___ ___/___ ___/ 20 ___ ___

B2. Individual who was unmasked (check all that apply):

a. ☐ Subject

c. ☐ Coordinator

d. ☐ QOL interviewer

e. ☐ Surgeon

f. ☐ Other (specify):_____

B3 What was the reason or event that caused the unmasking (check all that apply)?

a. ☐ adverse event →COMPLETE ADVERSE EVENTS FORM

b. ☐ additional treatment for urinary incontinence necessitated knowing the study intervention

c. ☐ patient demanded to know

d. ☐ inadvertent disclosure by surgeon or clinical staff

e. ☐ end of study

f. ☐ Other (specify):_____

B4. How did the unmasking occur?

a. ☐ Unmasking envelope opened

b. ☐ Electronic or Hard copy of medical record accessed

c. ☐ Verbally

Investigator/Coordinator Signature:_____ Date:___ ___/___ ___/ 20 ___ ___ (Month / Day / Year)

PFDN

OPUS

Form 15 Weekly Cath F/U

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

DCC ☐

Complete this form if a subject is using a catheter for urinary retention or was using a catheter at the previous contact.

SECTION B: Voiding function assessment

B1. Are you voiding spontaneously? 1. ☐ Yes 2. ☐ No

B2. Are you still using a catheter? 1. ☐ Yes → Go to B3 2. ☐ No

a. When did you stop using a catheter? ___ ___ / ___ ___ (Month / Day)

b. Why did you stop?
1. ☐ PVR≤150 cc
2. ☐ Instructed by clinician
3. ☐ Difficulty with catheterization
4. ☐ Bored/tired/didn't seem to need it
5. ☐ Other (Specify _____)

B3. Review the PVR record with the subject.

If subject fulfills the criterion for stopping (PVR≤150 cc), complete the following table with the qualifying results.

If subject does not fulfill criterion for stopping (PVR is >150 cc), record only the most recent day's results.

	Date (MM/DD)	Time	Urine Voided	PVR
a.	__ __/__ __	___ ___: ___ ___ 1. ☐ am 2. ☐ pm	___ ___ ___ ___ cc	___ ___ ___ cc
b.	__ __/__ __	___ ___: ___ ___ 1. ☐ am 2. ☐ pm	___ ___ ___ ___ cc	___ ___ ___ cc

B4. Do you attempt to void each time before you use the catheter? 1. ☐ Yes 2. ☐ No →

If response is NO, review the Self-Catheterization instructions with subject to insure correct procedure is followed.

B5. Subject fulfills the criteria for stopping catheterization (PVR <150cc) 1. ☐ Yes 2. ☐ No → Go to C1

a. Subject agrees to stop catheterization 1. ☐ Yes → Go to C1 2. ☐ No

If no, specify why _____

SECTION C: UTI symptom assessment

C1. In the past week have you been treated for a urinary tract infection? 1. ☐ Yes 2. ☐ No → Go to C2

a. Was a urinalysis performed? 1. ☐ Yes 2. ☐ No

If yes, complete Urine Test Results Form 19

b. Did you receive antibiotics? 1. ☐ Yes 2. ☐ No

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

C2. Are you taking antibiotics now? 1. ☐ Yes 2. ☐ No → Go to C4

C3. Reason for antibiotic therapy

1. ☐ Therapeutic antibiotic use for UTI treatment
2. ☐ Suppressive antibiotic use during urinary catheterization for retention
3. ☐ Not sure
4. ☐ Other, explain: _____

C4. Did the subject ask to speak with the doctor? 1. ☐ Yes 2. ☐ No

Investigator/ Coordinator Signature: _____ Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

PFDN

OPUS

Form 17 F/U MEDICAL HISTORY

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

A4. Visit: 1. ☐ 2 wk 2. ☐ 4-6 wk 3. ☐ 3 mo 4. ☐ 6 mo 5. ☐ 9 mo 6. ☐ 12 mo 7. ☐ other To DCC ☐

PLEASE ASK THE SUBJECT THE FOLLOWING QUESTIONS: *Date of last visit / call:* _____

B1. Since your last *visit/call* on *date*, have you been hospitalized overnight? 1. ☐ Yes → Complete Adverse Events Form 09A 2. ☐ No → Go to B2

a. Were any of these hospitalizations for a urologic condition (such as urinary tract infection or voiding trial), or for a gynecological condition (such as prolapse), or for complications/problems related to the treatment of these conditions?

1. ☐ Yes → Complete Table C1 2. ☐ No

B2. Since your last *visit/call* on *date*, have you had any outpatient surgery or an emergency room visit?

1. ☐ Yes 2. ☐ No → Go to B3

a. Were any of these visits, contacts or services for a urologic condition (such as urinary tract infection or post discharge voiding trial), or for a gynecological condition (such as prolapse), or for complications/problems related to the treatment of these conditions?

1. ☐ Yes → Complete Table C2 2. ☐ No

B3. Since your last *visit/call* on *date*, have you seen or contacted any doctor or health care professional? This would include calls or visits to a doctor's office, lab tests and any other medical services. 1. ☐ Yes 2. ☐ No → Go to B4

a. Were any of these visits, contacts or services for a urologic condition (such as urinary tract infection or post discharge voiding trial), or for a gynecological condition (such as prolapse), or for complications/problems related to the treatment of these conditions?

1. ☐ Yes → Complete Table C2 2. ☐ No

B4. Since your *last visit/call* on *date*, have you had any home health care services or stayed at a nursing home?

1. ☐ Yes 2. ☐ No → END

a. Were any of these visits, contacts or services for a urologic condition (such as urinary tract infection or post discharge voiding trial), or for a gynecological condition (such as prolapse), or for complications/problems related to the treatment of these conditions?

1. ☐ Yes → Complete Table C3 2. ☐ No → END

Coordinator: Query for the type and purpose of specific services. Ask for any diagnosis or procedure codes and descriptions on medical bills/reports from providers or insurers, if available. For the purpose of collecting cost data, please refer to the coding dictionary and appropriately characterize each service by specifying the corresponding inpatient, outpatient and nursing home/ home care codes in the code column and record the associated travel distance and work loss.
Please determine if resource use is for urologic/gynecologic diagnosis=Urogyn Dx, or complication of the index prolapse surgery=CC, or treatment of stress urinary incontinence=SUI, or treatment of urge urinary incontinence=UUI and check the applicable box(es) in the 'Relevance' column.

Coordinator Signature: _____ Date: __ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year)

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

A4. Visit: 1. ☐ 2 wk 2. ☐ 4-6 wk 3. ☐ 3 mo 4. ☐ 6 mo 5. ☐ 9 mo 6. ☐ 12 mo 7. ☐ other To DCC ☐

B5. Please provide a single Dindo Scoring for the most severe AE reported on this form. 77. ☐ NA

Score	Grade		Definition
☐	I		Any deviation from the normal intraoperative or postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
	II		Requiring pharmacological treatment with drugs other than such allowed for grade I complications.
☐		IIa	Oral administration of drugs other than such allowed for grade I, excluding antibiotics
☐		IIabx	Oral administration of drugs other than such allowed for grade I, including antibiotics
☐		IIb	IV administration of drugs other than such allowed for grade I, including antibiotics; blood transfusions and total parenteral nutrition are also included
	III		Requiring surgical, endoscopic or radiological intervention
☐		IIIo	Additional surgical measures required during OPUS Index procedure
☐		IIIa	Intervention not under general anesthesia
☐		IIIb	Intervention under general anesthesia
	IV		Life-threatening complication (including CNS complications)* requiring intermediate care or ICU management
☐		IVa	Single organ dysfunction (including dialysis)
☐		IVb	Multiorgan dysfunction
☐	V		Death of a patient
☐	Suffix "d"		If the patient suffers from a complication at the time of discharge, the suffix "d" (for "disability") is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

*Brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks.

Investigator/Coordinator Signature: _____ Date: __ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year)

PFDN

OPUS

Form 17 F/U MEDICAL HISTORY

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A3. Initials:___ ___ ___

A4. Visit: 1.☐ 2 wk 2.☐ 4-6 wk 3.☐ 3 mo 4.☐ 6 mo 5.☐ 9 mo 6.☐ 12 mo 7.☐ other To DCC ☐

C1. INPATIENT SERVICES USE: Please specify any relevant inpatient services used (use a separate row for each overnight hospital stay). Use ONE C1 code for each overnight hospital stay. If no C1 code is applicable, check the **Other → Specify** box then enter a description in 3rd column **Other → Specify**.

Seq. No.	Diagnosis	C1 Code	Other → Specify	Start Date (MM/DD/YYYY)	End Date (MM/DD/YYYY)	Relevance a.Urogyn Dx b.CC tx c.SUI tx d. UUI tx	Seen at this Clinical Site 1.Yes 2.No	Distance of travel to visit (roundtrip, in miles)	Days lost From work
11		_ _ _ 1.☐ Other → Specify		_ _/_ _/20_ _	_ _/_ _/20_ _	☐ ☐ ☐ ☐	1 2	_ _ _ . _	_ _ _ . _
12		_ _ _ 1.☐ Other → Specify		_ _/_ _/20_ _	_ _/_ _/20_ _	☐ ☐ ☐ ☐	1 2	_ _ _ . _	_ _ _ . _
13		_ _ _ 1.☐ Other → Specify		_ _/_ _/20_ _	_ _/_ _/20_ _	☐ ☐ ☐ ☐	1 2	_ _ _ . _	_ _ _ . _
14		_ _ _ 1.☐ Other → Specify		_ _/_ _/20_ _	_ _/_ _/20_ _	☐ ☐ ☐ ☐	1 2	_ _ _ . _	_ _ _ . _

Use additional forms if needed. Assign the Seq. No. consecutively. Submit completed pages at each visit. If more than one page required, indicate: Table C1. page __ of __
On additional pages, replace the sequence numbers by new 2-digit numbers not used in any table of this form. Check the code list for possible 'C1 codes'.

PFDN

OPUS

Form 17 F/U MEDICAL HISTORY

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A3. Initials:___ ___ ___

A4. Visit: 1.☐ 2 wk 2.☐ 4-6 wk 3.☐ 3 mo 4.☐ 6 mo 5.☐ 9 mo 6.☐ 12 mo 7.☐ other To DCC ☐

C2. Outpatient Service Use: Please specify any relevant outpatient services used, such as office visits (specify whether it is with a physician or other health care provider), lab tests, diagnostic procedures, outpatient surgery, accidental injury, emergency room visit, physical therapy, specialty services, pre-admission testing, etc. (Record each visit or encounter on a separate row. For each visit or encounter, use multiple C2 codes when applicable.). If you cannot find a suitable C2 code from the code list for one or more service items, check the **Other->Specify** box and give their description(s) in the 3rd column **Other->Specify**.

Seq. No.	Diagnosis	C2 Code	Other → Specify	Start Date (MM/DD/YYYY)	Relevance a.Urogyn b.CC c.SUI d.UUI Dx tx tx tx	Seen at this Clinical Site 1.Yes 2.No	Distance of travel to visit (roundtrip, in miles)	Days lost From work
21		_ _ _ _ _ _ _ _ _ _ _ _ 1.☐ Other → Specify		_ _/_ _/20_ _	☐ ☐ ☐ ☐	1 2	_ _ _ . _	_ _ _ . _
22		_ _ _ _ _ _ _ _ _ _ _ _ 1.☐ Other → Specify		_ _/_ _/20_ _	☐ ☐ ☐ ☐	1 2	_ _ _ . _	_ _ _ . _
23		_ _ _ _ _ _ _ _ _ _ _ _ 1.☐ Other → Specify		_ _/_ _/20_ _	☐ ☐ ☐ ☐	1 2	_ _ _ . _	_ _ _ . _
24		_ _ _ _ _ _ _ _ _ _ _ _ 1.☐ Other → Specify		_ _/_ _/20_ _	☐ ☐ ☐ ☐	1 2	_ _ _ . _	_ _ _ . _

Use additional forms if needed. Assign the Seq. No. consecutively. Submit all completed pages at each visit. If more than one page required, indicate: Table C2. page __ of __.
On additional pages, replace the sequence numbers by new 2-digit numbers not used in any table of this form. Check the code list for possible 'C2 codes'.

PFDN

OPUS

Form 17 F/U MEDICAL HISTORY

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A3. Initials:___ ___ ___

A4. Visit: 1.☐ 2 wk 2.☐ 4-6 wk 3.☐ 3 mo 4.☐ 6 mo 5.☐ 9 mo 6.☐ 12 mo 7.☐ other To DCC ☐

C3. NURSING HOME OR RELEVANT HOME HEALTH USE: Please specify any relevant overnight stay at a nursing home or any relevant home health care (use a separate row for each spell of nursing home stay or each home health care visit). Use ONE C3 code for each nursing home stay or home healthcare visit . If no C3 code is applicable, check the Other → Specify box then enter a description in 3rd column Other → Specify.

Seq. No.	Diagnosis	C3. Code	Other → Specify	Start Date (MM/DD/YYYY)	Nursing Home # of nights	Home Health Care # of hours	Relevance a Urogyn UUI Dx ☐ b.CC tx ☐ c.SUI tx ☐ d. tx ☐	At this Clinical Site 1.Yes 2.No	Distance of travel to visit (roundtrip, in miles)	Days lost From work
31		_ _ _ 1. ☐ Other → Specify		_ _ /_ _ /20_ _	_ _ _	_ _ _	☐ ☐ ☐ ☐	1. 2.	_ _ _ . _	_ _ _ . _
32		_ _ _ 1. ☐ Other → Specify		_ _ /_ _ /20_ _	_ _ _	_ _ _	☐ ☐ ☐ ☐	1 2	_ _ _ . _	_ _ _ . _
33		_ _ _ 1. ☐ Other → Specify		_ _ /_ _ /20_ _	_ _ _	_ _ _	☐ ☐ ☐ ☐	1. 2.	_ _ _ . _	_ _ _ . _
34		_ _ _ 1. ☐ Other → Specify		_ _ /_ _ /20_ _	_ _ _	_ _ _	☐ ☐ ☐ ☐	1 2	_ _ _ . _	_ _ _ . _

Use additional forms if needed. Assign the Seq. No. consecutively. Submit all completed pages at each visit. If more than one page required, indicate Table C3. page __ of __.
On additional pages, replace the sequence numbers by new 2-digit numbers not used in any table of this form. Check the code list for possible 'C3 codes'.

PFDN **OPUS** Form 18 Non-Medical / Productivity Loss

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

A4. Visit: 1. ☐ Baseline 2. ☐ 3 mo 3. ☐ 6 mo 4. ☐ 9 mo 5. ☐ 12 mo DCC ☐

We would like to learn whether any urologic or gynecologic condition has affected your daily life.

B0. (At 3 month call only; however, if the 3 mo call is missed, ask at 6 mo)
How many weeks or days did you not go to work following the original prolapse surgery?

___ ___ weeks OR ___ ___ days (Enter "0" if patient was not working for pay at the time)

B1. Are you doing any work for pay at the present time, including self-employment?
1. ☐ Yes 2. ☐ No → Go to B4

a. How many hours per week do you usually work? ___ ___ hours per week

b. How many days per week do you usually work? ___ . ___ days per week

B2. In the past month, how many days of work did you miss because of any urologic or gynecologic condition, treatment of these conditions, or any complications associated with these treatments?

PROBES: Think about the work days you missed in order to seek health care for these reasons. Think about the days when you had to stay at home because of these reasons or recovery from treatments.
___ ___ days (Enter "0" if patient did not miss any work because of these reasons)

B3. In the past month, were there any days when you felt you were less than fully productive at work because of any urologic or gynecologic condition, treatment of these conditions, or any complications associated with these treatments?
1. ☐ Yes 2. ☐ No → Go to B5

a. In the past month, about how many days at work did you feel that you were less than fully productive because of these reasons?
___ ___ Days (convert to days if patients report hours or less than one day, e.g., 0.5 day)

b. During THOSE days over the past month when you were not as productive at work, how would you rate your average level of effectiveness on a scale from 1 to 10 where 1 represents "not at all effective" and 10 represents "fully effective"?
___ ___ (Specify 1-10) → Go to B5

B4. You said that you are NOT currently working for pay. Is it because of any urologic or gynecologic condition, treatment of these conditions, or any complications associated with these treatments?
1. ☐ Yes 2. ☐ No → Go to B5

a. When did you stop working because of these reasons? ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

B5. In the past week, how many hours of routine household chores (e.g., house keeping, yard work, etc.) that you usually perform but were unable to do because of a urologic/gynecologic condition, treatment of these conditions, or any complications associated with these treatments, including the original prolapse surgery?

___ ___ hours (Enter "0" if these health conditions did not affect household work)

B6. In the past week, did you experience involuntary urinary leakage related to coughing, sneezing, laughing, lifting, bending over, or physical exercise (such as walking, running, aerobics, or tennis), or urinary leakage associated with a feeling of urgency (that is, a strong sensation of needing to go to the bathroom?
1. ☐ Yes 2. ☐ No →END

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

B7. For each of the following incontinence products, how many did you use specifically for your urinary leakage in the past week?

Product Type	Ever Used in the Past Week 1.Yes	2.No	Average Number Used per Day during the Past Week
Paper towels/Toilet paper/Self made pads	1.	2.	___ ___ pads
Panty liners/minipads	1.	2.	___ ___ liners/minipads
Menstrual pads	1.	2.	___ ___ pads
Incontinence pads	1.	2.	___ ___ pads
Adult diapers/Incontinence briefs/pull-ups	1.	2.	___ ___ diapers/briefs
Underpads for your bed	1.	2.	___ ___ underpads
Incontinence skin care	1.	2.	___ ___
Other (specify: _____)	1.	2.	___ ___
Other (specify: _____)	1.	2.	___ ___

B8. In the past week, how many additional loads of laundry did you do because of your urinary leakage?

___ ___ loads (Enter "0" if no additional laundry because of urinary leakage)

B9. In the past week, how many additional items of clothing did you dry clean because of your urinary leakage?

___ ___ items (Enter "0" if no additional dry clean because of urinary leakage)

Investigator/ Coordinator Signature: _____ Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

PFDN

OPUS

Form 19 Urine Test Results

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year) A3. Initials: ___ ___ ___

A4. Visit: 1. ☐ 2 wk 2. ☐ 4-6 wk 3. ☐ 3 mo 4. ☐ 6 mo 5. ☐ 9 mo 6. ☐ 12 mo 7. ☐ other DCC ☐

Use this form to report urine tests results obtained at any follow up contact

SECTION B:

B1. Subject is catheterizing 1. ☐ Yes 2. ☐ No

B2. Subject is taking antibiotics for a urinary tract infection 1. ☐ Yes 2. ☐ No

B3. Subject is taking antibiotics for suppression 1. ☐ Yes 2. ☐ No

B4. Subject is taking antibiotics for another reason 1. ☐ Yes 2. ☐ No

a. If yes, specify _____

SECTION C: Urine dipstick

88. ☐ Not done

C1. Date dipstick test was performed: ___ ___/___ ___/___ ___ ___ ___ (Month / Day / Year)

C2. Dipstick test results (positive is greater than trace) for

a. white blood cells (WBCs or leukocytes or leukocyte esterase) 1. ☐ Positive 2. ☐ Negative

b. nitrites 1. ☐ Positive 2. ☐ Negative

c. red blood cells (RBCs or hemoglobin) 1. ☐ Positive 2. ☐ Negative

Note: The dipstick test is positive if WBC or nitrites are greater than trace.

SECTION D: Microscopic urinalysis

88. ☐ Not done

D1. Date microscopic urinalysis was performed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

D2. Microscopic urinalysis data (check all that apply)

a. ☐ WBC _____ per high-power field

b. ☐ RBC _____ per high-power field

c. ☐ Bacteria _____

d. ☐ none of the above

SECTION E: Culture

88. ☐ Not done

E1. Date urine culture was performed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

E2. Urine culture 1. ☐ Positive ($\geq 10^3$) 2. ☐ Negative →END

E3. Positive urine culture bacterial species:

a. ☐	Escherichia coli	→	1. ☐ 10^3	2. ☐ 10^4	3. ☐ $\geq 10^5$
b. ☐	Klebsiella pneumoniae	→	1. ☐ 10^3	2. ☐ 10^4	3. ☐ $\geq 10^5$
c. ☐	Proteus mirabilis	→	1. ☐ 10^3	2. ☐ 10^4	3. ☐ $\geq 10^5$
d. ☐	Streptococcus agalactiae	→	1. ☐ 10^3	2. ☐ 10^4	3. ☐ $\geq 10^5$
e. ☐	Staphylococcus aureus	→	1. ☐ 10^3	2. ☐ 10^4	3. ☐ $\geq 10^5$
f. ☐	Other, Specify _____	→	1. ☐ 10^3	2. ☐ 10^4	3. ☐ $\geq 10^5$

Investigator/ Coordinator Signature: _____ Date: ___ ___ / ___ ___ / 20 ___ ___ (Month / Day / Year)

A1. Site/Study ID #: ___ ___ / R ___ ___ ___ ___

A2. Initials:___ ___ ___

Online Entry ☐

SECTION B: Subject Status Change from RCT to PPT participation

B1. Subject signed consent to PPT participation ___ ___ / ___ ___ / 20___ ___

B2. PPT Subject ID assigned ___ ___ / N___ ___ ___ ____

B3. Please specify the reason for this subject's change from RCT to PPT:

1. ☐ Subject wants surgeon to choose procedure
2. ☐ Subject wants TVT
3. ☐ Subject does not want TVT
4. ☐ Subject changed her mind, no reason given
5. ☐ Other, Specify:_____

Investigator/ Coordinator Signature:_____ Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

PFDN

OPUS

Form 20 Final Status

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___

A2. Initials:___ ___ ___

Online Entry ☐ DCC ☐

SECTION B: Final Subject Status

B1. Status:

1. ☐ Completed study (Completed 12 month clinic visit and/or 12 month QOL interview) → END

Withdrawal:

2. ☐ Ineligible/Screen failure
3. ☐ Withdrew consent prior to randomization
4. ☐ Subject voluntarily withdrew from study ___ ___ / ___ ___ / 20___ ___ (Date of decision to withdraw)
5. ☐ Investigator withdrew subject from study ___ ___ / ___ ___ / 20___ ___ (Date of decision to withdraw)
6. ☐ Lost to follow-up ___ ___ / ___ ___ / 20___ ___ (Date of last contact)
7. ☐ Death (Complete Form 09A) ___ ___ / ___ ___ / 20___ ___ (Date of death) 66. ☐ UNK
8. ☐ Study terminated
9. ☐ Other ___ ___ / ___ ___ / 20___ ___ (Date of event)

B2. Please specify the reason for this subject's withdrawal from the OPUS study:

_____

_____

Investigator/ Coordinator Signature:_____ Date: ___ ___ / ___ ___ / 20 ___ ___
Month Day Year

PFDN **OPUS** Form 22C CMS-1500

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Sequence #: C - _____ A3. Initials:___ ___ ___ DCC ☐

B1.

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES

FROM ___ ___ / ___ ___ / 20 ___ ___ (MM DD YY) TO ___ ___ / ___ ___ / 20 ___ ___ (MM DD YY)

B2.

19. RESERVED FOR LOCAL USE

B3. Alphanumeric ICD diagnosis codes (*enter codes left justified*)

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY

1. ____ ____ ____ ____ ____ ____ ____

2. ____ ____ ____ ____ ____ ____ ____

3. ____ ____ ____ ____ ____ ____ ____

4. ____ ____ ____ ____ ____ ____ ____

B4. Service details

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE 2-digit code	D. PROCEDURES, SERVICES, OR SUPPLIES CPT/HCPCS 5-digit alphanumeric code	MODIFIER 2-digit alphanumeric code, up to four modifiers per row				G. DAYS OR UNITS
1 __ __ / __ __ / 20 __ __	__ __ / __ __ / 20 __ __	__ __	__ __ __ __ __	__ __	__ __	__ __	__ __	
2 __ __ / __ __ / 20 __ __	__ __ / __ __ / 20 __ __	__ __	__ __ __ __ __	__ __	__ __	__ __	__ __	
3 __ __ / __ __ / 20 __ __	__ __ / __ __ / 20 __ __	__ __	__ __ __ __ __	__ __	__ __	__ __	__ __	
4 __ __ / __ __ / 20 __ __	__ __ / __ __ / 20 __ __	__ __	__ __ __ __ __	__ __	__ __	__ __	__ __	
5 __ __ / __ __ / 20 __ __	__ __ / __ __ / 20 __ __	__ __	__ __ __ __ __	__ __	__ __	__ __	__ __	
6 __ __ / __ __ / 20 __ __	__ __ / __ __ / 20 __ __	__ __	__ __ __ __ __	__ __	__ __	__ __	__ __	

PFDN

OPUS

Form 22U UB-04

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Sequence #: U - _____ A3. Initials:___ ___ ___ DCC ☐

B1.

4 TYPE OF BILL	6 STATEMENT COVERS PERIOD FROM MM DD YY	THROUGH MM DD YY	12 ADMISSION DATE MM DD YY	17 STAT two-digit alphanumeric code
0 ___ ___ ___	__ __ /__ __/ 20__ __	__ __ /__ __/ 20__ __	__ __ /__ __/ 20__ __	____ ____

B2.

	42 REV. CD. four-digit code	43 DESCRIPTION	44 HCPCS/RATE/HIPPS CODE five-digit HCPCS/HIPPS code	two-digit modifier, after the HCPCS/HIPPS code				45 SERV. DATE MM DD YY	46 SERV. UNITS
1	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
2	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
3	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
4	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
5	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
6	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
7	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
8	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
9	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
10	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
11	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
12	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
13	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
14	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
15	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
16	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
17	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
18	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
19	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
20	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
21	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
22	___ ___ ___ ___		___ ___ ___ ___ ___	___ ___	___ ___	___ ___	___ ___	__ __ /__ __/ 20__ __	
								CREATION DATE __ __ /__ __/ 20__ __	

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Sequence #: U - _____ A3. Initials:___ ___ ___ DCC ☐

B3. Alphanumeric diagnosis codes (*enter codes left justified*), with Present on Admission indicator *entered in shaded area* (if present)

66 DX	67	A	B	C	D	E	F	G	H
	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _
___	I	J	K	L	M	N	O	P	Q
	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _	_ _ _ _ _ _ _ _

B4. Three-digit alphanumeric DRG code

71 PPS CODE	_____ _____ _____

B5. Alphanumeric procedure codes (*enter codes left justified*)

74 PRINCIPAL PROCEDURE CODE	DATE MM DD YY	a. OTHER PROCEDURE CODE	DATE MM DD YY	b. OTHER PROCEDURE CODE	DATE MM DD YY
___ ___ ___ ___ ___ ___ ___	__ __/__ __/ 20__ __	___ ___ ___ ___ ___ ___ ___	__ __/__ __/ 20__ __	___ ___ ___ ___ ___ ___ ___	__ __/__ __/ 20__ __
c OTHER PROCEDURE CODE	DATE MM DD YY	d OTHER PROCEDURE CODE	DATE MM DD YY	e OTHER PROCEDURE CODE	DATE MM DD YY
___ ___ ___ ___ ___ ___ ___	__ __/__ __/ 20__ __	___ ___ ___ ___ ___ ___ ___	__ __/__ __/ 20__ __	___ ___ ___ ___ ___ ___ ___	__ __/__ __/ 20__ __

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

We'll begin with some general questions about how you've been feeling

1. In general, would you say your health is:

1	Excellent
2	Very Good
3	Good
4	Fair
5	Much worse than one year ago

2. Compared to one year ago, how would you rate your health in general now?

1	Much better now than one year ago
2	Somewhat better now than one year ago
3	About the same as one year ago
4	Somewhat worse than one year ago
5	Much worse than one year ago

The following items are activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. Vigorous activities such as running, lifting heavy objects, participating in strenuous sports?	1	2	3
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	1	2	3
5. Lifting or carrying groceries?	1	2	3
6. Climbing several flights of stairs?	1	2	3
7. Climbing one flight of stairs?	1	2	3
8. Bending, kneeling, or stooping?	1	2	3
9. Walking more than a mile?	1	2	3
10. Walking several hundred yards?	1	2	3
11. Walking one hundred yards?	1	2	3
12. Bathing or dressing yourself?	1	2	3

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

During the past four weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
13. Cut down the amount of time you spent on work or other activities?	1	2	3	4	5
14. Accomplished less than you would like?	1	2	3	4	5
15. Were limited in the kind of work or other activities?	1	2	3	4	5
16. Had difficulty performing work or other activities (for example, it took extra effort)?	1	2	3	4	5

During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
17. Cut down the amount of time you spent on work or other activities?	1	2	3	4	5
18. Accomplished less than you would like?	1	2	3	4	5
19. Did work or other activities less carefully than usual?	1	2	3	4	5

20. During the past four weeks, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

1 Not at all 2 Slightly 3 Moderately 4 Quite a bit 5 Extremely

21. How much bodily pain have you had during the past four weeks?

1 None 2 Very Mild 3 Mild 4 Moderate 5 Severe 6 Very Severe

22. During the past four weeks, how much did pain interfere with your normal work (including both work outside the home and housework

1 Not at all 2 A little bit 3 Moderately 4 Quite a bit 5 Extremely

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

The next questions are about how you feel and how things have been with you during the past four weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
23. How much of the time during the past four weeks did you feel full of life?	1	2	3	4	5
24. How much of the time during the past four weeks have you been very nervous?	1	2	3	4	5
25. How much of the time during the past four weeks have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
26. How much of the time during the past four weeks have you felt calm and peaceful?	1	2	3	4	5
27. How much of the time during the past four weeks did you have a lot of energy?	1	2	3	4	5
28. How much of the time during the past four weeks have you felt downhearted and depressed?	1	2	3	4	5
29. How much of the time during the past four weeks did you feel worn out?	1	2	3	4	5
30. How much of the time during the past four weeks have you been happy?	1	2	3	4	5
31. How much of the time during the past four weeks did you feel tired?	1	2	3	4	5
32. During the past four weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?	1	2	3	4	5

Thank you for going through those questions with me. In this next section, I'd like you to indicate how true or false each of the following statements is for you.

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people.	1	2	3	4	5
34. I am as healthy as anybody I know.	1	2	3	4	5
35. I expect my health to get worse.	1	2	3	4	5
36. My health is excellent.	1	2	3	4	5

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

Please indicate which statements best describe your own health state today.

1. Mobility

1	I have no problems in walking about
2	I have some problems in walking about
3	I am confined to bed

2. Self-Care

1	I have no problems with self-care
2	I have some problems washing or dressing myself
3	I am unable to wash or dress myself

3. Usual Activities (e.g. work, study, housework, family or leisure activities)

1	I have no problems with performing my usual activities
2	I have some problems with performing my usual activities
3	I am unable to perform my usual activities

4. Pain/Discomfort

1	I have no pain or discomfort
2	I have moderate pain or discomfort
3	I have extreme pain or discomfort

5. Anxiety/Depression

1	I am not anxious or depressed
2	I am moderately anxious or depressed
3	I am extremely anxious or depressed

6. On a scale from 0 to 100, where zero represents “worst imaginable health state” and “100” represents “best imaginable health state”, please tell me what number would represent how good or bad your health state is today.

___ ___ ___
(Single number only, no ranges)

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

1. During the past month, on average, on how many days in each week did you do strenuous or very hard exercise; that is, exercise that caused you to work up a sweat and made your heart beat fast. For example, aerobics, dancing, jogging, or tennis?

   ___ days a week (single number, no range)

   a. In general, how many minutes each day did you do this exercise

      __ __ __ minutes each day (Single number only, no ranges)

2. During the past month, how often did you perform physical activities that required a major effort, such as lifting heavy furniture, shoveling snow, or lifting people or objects weighing more than 25 lbs?

1	Never
2	Once a month
3	Two to three times a month
4	Once a week
5	More than once a week

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ 3 mo 2. ☐ 6 mo 3.☐ 12 mo

NOT COMPLETED AT BASELINE, AFTER SURGERY ONLY

1. What best describes how your bladder function is now, compared to how it was before you had prolapse surgery?

1	Very much better
2	Much better
3	A little better
4	No change
5	A little worse
6	Much worse
7	Very much worse

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

1. How often do you experience urinary leakage?

0	Never → END this page
1	Less than once per month
2	A few times a month
3	A few times a week
4	Every day and/or night

2. How much urine do you lose each time?

1	Drops
2	Small splashes
3	More

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

Next, I'd like to ask you about problems you may experience in your pelvic area.

			If yes, how much does this bother you?			
	1. No	2. Yes	Not at all	Somewhat	Moderately	Quite a bit
1. Do you usually experience pressure in the lower abdomen?	No	Yes →	1	2	3	4
2. Do you usually experience pain in the lower abdomen or genital area?	No	Yes →	1	2	3	4
3. Do you usually experience heaviness or dullness in the pelvic area?	No	Yes →	1	2	3	4
4. Do you usually have a sensation of bulging or protrusion from the vaginal area?	No	Yes →	1	2	3	4
5. Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?	No	Yes →	1	2	3	4
6. Do you usually experience pelvic discomfort when standing or physically exerting yourself?	No	Yes →	1	2	3	4
7. Do you usually experience pain in your lower back on most days?	No	Yes →	1	2	3	4
8. Do you usually have to push on the vagina or around the rectum to have or complete a bowel movement?	No	Yes →	1	2	3	4
9. Do you usually feel you need to strain too hard to have a bowel movement?	No	Yes →	1	2	3	4
10. Do you usually feel you have not completely emptied your bowels at the end of a bowel movement?	No	Yes →	1	2	3	4
11. Do you usually experience difficulty emptying your bladder?	No	Yes →	1	2	3	4
12. Do you usually experience a feeling of incomplete bladder emptying?	No	Yes →	1	2	3	4
13. Do you usually feel that you have an unusually weak stream or that you take too long to empty your bladder?	No	Yes →	1	2	3	4

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

	1. No	2. Yes	If yes, how much does this bother you? Not at all	Somewhat	Moderately	Quite a bit
14. When you urinate, does your stream usually start and stop and start again before you are finally finished?	No	Yes →	1	2	3	4
15. Do you usually have to assume an unusual position or change positions to start or complete urination?	No	Yes →	1	2	3	4
16. Do you usually have to push up on a bulge in the vaginal area with your fingers to start or complete urination?	No	Yes →	1	2	3	4
17. Do you usually experience frequent urination?	No	Yes →	1	2	3	4
18. Do you usually experience a strong feeling of urgency to empty your bladder?	No	Yes →	1	2	3	4
19. Do you usually experience urine leakage associated with a feeling of urgency, that is, a strong sensation of needing to go to the bathroom?	No	Yes →	1	2	3	4
20. Do you usually experience urine leakage related to coughing, sneezing, or laughing?	No	Yes →	1	2	3	4
21. Do you usually experience urine leakage related to physical exercise such as walking, running, aerobics, or tennis?	No	Yes →	1	2	3	4
22. Do you usually experience urine leakage related to lifting or bending over?	No	Yes →	1	2	3	4
23. Do you usually experience urine leakage when you go from sitting to standing?	No	Yes →	1	2	3	4
24. Do you usually experience urine leakage not related to urgency or physical activity?	No	Yes →	1	2	3	4
25. Do you usually experience small amounts of urine leakage (that is, drops)?	No	Yes →	1	2	3	4

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

	1. No	2. Yes	If yes, how much does this bother you? Not at all	Somewhat	Moderately	Quite a bit
26. Do you usually experience large amounts of urine leakage?	No	Yes →	1	2	3	4
27. Do you usually awaken during your normal sleeping hours to urinate?	No	Yes →	1	2	3	4
28. Do you usually experience bed-wetting?	No	Yes →	1	2	3	4
29. Do you usually experience pain or burning when urinating?	No	Yes →	1	2	3	4
30. Do you usually lose urine during sexual activity?	No	Yes →	1	2	3	4
31. Do you usually have to push on your lower abdomen to start or complete urination?	No	Yes →	1	2	3	4
32. Do you usually dribble urine as you stand up or begin to walk immediately after you have finished urinating?	No	Yes →	1	2	3	4
33. Do you usually experience pain in the middle of your lower abdomen as your bladder fills?	No	Yes →	1	2	3	4
34. Do you usually experience pressure in the middle of your lower abdomen as your bladder fills?	No	Yes →	1	2	3	4
35. Do you usually have abdominal pain prior to bowel movements?	No	Yes →	1	2	3	4
36. Do you usually experience loss of gas or stool as the result of physically stressful activities such as with exercise, coughing, sneezing, or hard laughing?	No	Yes →	1	2	3	4
37. Do you usually experience loss of gas or stool after a sense of urgency or after another warning sensation?	No	Yes →	1	2	3	4

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

			If yes, how much does this bother you?			
	1. No	2. Yes	Not at all	Somewhat	Moderately	Quite a bit
38. Do you usually lose stool beyond your control if your stool is well formed?	No	Yes →	1	2	3	4
39. Do you lose stool beyond your control if your stool is loose or liquid?	No	Yes →	1	2	3	4
40. Do you usually lose gas from the rectum beyond your control?	No	Yes →	1	2	3	4
41. Do you usually have pain when you pass your stool?	No	Yes →	1	2	3	4
42. Do you usually experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?	No	Yes →	1	2	3	4
43. Do you usually pass mucus with or in your bowel movement?	No	Yes →	1	2	3	4
44. Do you usually have hemorrhoids?	No	Yes →	1	2	3	4
45. Does a part of your bowel usually pass through the rectum and bulge outside during or after a bowel movement?	No	Yes →	1	2	3	4
46. Do you usually experience abdominal or lower back pain when you strain for any reason (for example with a bowel movement, or when lifting a heavy object)?	No	Yes →	1	2	3	4

Thank you. I appreciate you going through those sensitive questions with me. Your answers are very important to our research.

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

Some women find that bladder, bowel, or vaginal symptoms affect their activities, relationships and feelings. The next set of questions has to do with areas in your life which may have been affected by your bladder, bowel or vaginal symptoms. Please tell me the one answer that best describes you and your situation.

		Not at all	Somewhat	Moderately	Quite a bit
1a.	How do your bladder or urine symptoms usually affect your ability to do household chores (cooking, housecleaning, laundry)?	1	2	3	4
1b.	How do your bowel or rectum symptoms usually affect your ability to do household chores (cooking, housecleaning, laundry)?	1	2	3	4
1c.	How do your pelvic or vaginal symptoms usually affect your ability to do household chores (cooking, housecleaning, laundry)?	1	2	3	4
2a.	How do your bladder or urine symptoms usually affect your ability to do usual maintenance or repair work in your home or yard?	1	2	3	4
2b.	How do your bowel or rectum symptoms usually affect your ability to do usual maintenance or repair work in your home or yard?	1	2	3	4
2c.	How do your pelvic or vaginal symptoms usually affect your ability to do usual maintenance or repair work in your home or yard?	1	2	3	4
3a.	How do your bladder or urine symptoms usually affect your shopping activities?	1	2	3	4
3b.	How do your bowel or rectum symptoms usually affect your shopping activities?	1	2	3	4
3c.	How do your pelvic or vaginal symptoms usually affect your shopping activities?	1	2	3	4

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

		Not at all	Somewhat	Moderately	Quite a bit
4a.	How do your bladder or urine symptoms usually affect your hobby and pastime activities?	1	2	3	4
4b.	How do your bowel or rectum symptoms usually affect your hobby and pastime activities?	1	2	3	4
4c.	How do your pelvic or vaginal symptoms usually affect your hobby and pastime activities?	1	2	3	4
5a.	How do your bladder or urine symptoms usually affect your ability to do physical activities such as walking, swimming or other exercise?	1	2	3	4
5b.	How do your bowel or rectum symptoms usually affect your ability to do physical activities such as walking, swimming or other exercise?	1	2	3	4
5c.	How do your pelvic or vaginal symptoms usually affect your ability to do physical activities such as walking, swimming or other exercise?	1	2	3	4
6a.	How do your bladder or urine symptoms usually affect your entertainment activities such as going to a movie or concert?	1	2	3	4
6b.	How do your bowel or rectum symptoms usually affect your entertainment activities such as going to a movie or concert?	1	2	3	4
6c.	How do your pelvic or vaginal symptoms usually affect your entertainment activities such as going to a movie or concert?	1	2	3	4
7a.	How do your bladder or urine symptoms usually affect your ability to travel by car or bus for distances less than 20 minutes away from home?	1	2	3	4
7b.	How do your bowel or rectum symptoms usually affect your ability to travel by car or bus for distances less than 20 minutes away from home?	1	2	3	4
7c.	How do your pelvic or vaginal symptoms usually affect your ability to travel by car or bus for distances less than 20 minutes away from home?	1	2	3	4

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

		Not at all	Somewhat	Moderately	Quite a bit
8a.	How do your bladder or urine symptoms usually affect your ability to travel by car or bus for a distance greater than 20 minutes away from home?	1	2	3	4
8b.	How do your bowel or rectum symptoms usually affect your ability to travel by car or bus for a distance greater than 20 minutes away from home?	1	2	3	4
8c.	How do your pelvic or vaginal symptoms usually affect your ability to travel by car or bus for a distance greater than 20 minutes away from home?	1	2	3	4
9a.	How do your bladder or urine symptoms usually affect your going to places if you are not sure about available restrooms?	1	2	3	4
9b.	How do your bowel or rectum symptoms usually affect your going to places if you are not sure about available restrooms?	1	2	3	4
9c.	How do your pelvic or vaginal symptoms usually affect your going to places if you are not sure about available restrooms?	1	2	3	4
10a.	How do your bladder or urine symptoms usually affect your going on vacation?	1	2	3	4
10b.	How do your bowel or rectum symptoms usually affect your going on vacation?	1	2	3	4
10c.	How do your pelvic or vaginal symptoms usually affect your going on vacation?	1	2	3	4
11a.	How do your bladder or urine symptoms usually affect your church or temple attendance?	1	2	3	4
11b.	How do your bowel or rectum symptoms usually affect your church or temple attendance?	1	2	3	4
11c.	How do your pelvic or vaginal symptoms usually affect your church or temple attendance?	1	2	3	4

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

		Not at all	Somewhat	Moderately	Quite a bit
12a.	How do your bladder or urine symptoms usually affect your volunteer activities?	1	2	3	4
12b.	How do your bowel or rectum symptoms usually affect your volunteer activities?	1	2	3	4
12c.	How do your pelvic or vaginal symptoms usually affect your volunteer activities?	1	2	3	4
13a.	How do your bladder or urine symptoms usually affect your employment (work) outside the home?	1	2	3	4
13b.	How do your bowel or rectum symptoms usually affect your employment (work) outside the home?	1	2	3	4
13c.	How do your pelvic or vaginal symptoms usually affect your employment (work) outside the home?	1	2	3	4
14a.	How do your bladder or urine symptoms usually affect your having friends visit you in your home?	1	2	3	4
14b.	How do your bowel or rectum symptoms usually affect your having friends visit you in your home?	1	2	3	4
14c.	How do your pelvic or vaginal symptoms usually affect your having friends visit you in your home?	1	2	3	4
15a.	How do your bladder or urine symptoms usually affect your participating in social activities outside your home?	1	2	3	4
15b.	How do your bowel or rectum symptoms usually affect your participating in social activities outside your home?	1	2	3	4
15c.	How do your pelvic or vaginal symptoms usually affect your participating in social activities outside your home?	1	2	3	4

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

		Not at all	Somewhat	Moderately	Quite a bit
16a.	How do your bladder or urine symptoms usually affect your relationship with friends?	1	2	3	4
16b.	How do your bowel or rectum symptoms usually affect your relationship with friends?	1	2	3	4
16c.	How do your pelvic or vaginal symptoms usually affect your relationship with friends?	1	2	3	4
17a.	How do your bladder or urine symptoms usually affect your relationship with family excluding your husband/companion?	1	2	3	4
17b.	How do your bowel or rectum symptoms usually affect your relationship with family excluding your husband/companion?	1	2	3	4
17c.	How do your pelvic or vaginal symptoms usually affect your relationship with family excluding your husband/companion?	1	2	3	4
18a.	How do your bladder or urine symptoms usually affect your relationship with your husband or intimate companion?	1	2	3	4
18b.	How do your bowel or rectum symptoms usually affect your relationship with your husband or intimate companion?	1	2	3	4
18c.	How do your pelvic or vaginal symptoms usually affect your relationship with your husband or intimate companion?	1	2	3	4
19a.	How do your bladder or urine symptoms usually affect your ability to have sexual relations?	1	2	3	4
19b.	How do your bowel or rectum symptoms usually affect your ability to have sexual relations?	1	2	3	4
19c.	How do your pelvic or vaginal symptoms usually affect your ability to have sexual relations?	1	2	3	4

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

		Not at all	Somewhat	Moderately	Quite a bit
20a.	How do your bladder or urine symptoms usually affect the way you dress?	1	2	3	4
20b.	How do your bowel or rectum symptoms usually affect the way you dress?	1	2	3	4
20c.	How do your pelvic or vaginal symptoms usually affect the way you dress?	1	2	3	4
21a.	How do your bladder or urine symptoms usually affect your emotional health?	1	2	3	4
21b.	How do your bowel or rectum symptoms usually affect your emotional health?	1	2	3	4
21c.	How do your pelvic or vaginal symptoms usually affect your emotional health?	1	2	3	4
22a.	How do your bladder or urine symptoms usually affect your physical health?	1	2	3	4
22b.	How do your bowel or rectum symptoms usually affect your physical health?	1	2	3	4
22c.	How do your pelvic or vaginal symptoms usually affect your physical health?	1	2	3	4
23a.	How do your bladder or urine symptoms usually affect your sleep?	1	2	3	4
23b.	How do your bowel or rectum symptoms usually affect your sleep?	1	2	3	4
23c.	How do your pelvic or vaginal symptoms usually affect your sleep?	1	2	3	4

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

		Not at all	Somewhat	Moderately	Quite a bit
24a.	Does fear of urine odor restrict your activities?	1	2	3	4
24b.	Does fear of bowel odor restrict your activities?	1	2	3	4
24c.	Does fear of vaginal odor restrict your activities?	1	2	3	4
25a.	Does fear of embarrassment due to bladder or urine symptoms restrict your activities?	1	2	3	4
25b.	Does fear of embarrassment due to bowel or rectum symptoms restrict your activities?	1	2	3	4
25c.	Does fear of embarrassment due to pelvic or vaginal symptoms restrict your activities?	1	2	3	4
26a.	Do your bladder or urine symptoms cause you to experience feelings of nervousness or anxiety?	1	2	3	4
26b.	Do your bowel or rectum symptoms cause you to experience feelings of nervousness or anxiety?	1	2	3	4
26c.	Do your pelvic or vaginal symptoms cause you to experience feelings of nervousness or anxiety?	1	2	3	4
27a.	Do your bladder or urine symptoms cause you to experience feelings of fear?	1	2	3	4
27b.	Do your bowel or rectum symptoms cause you to experience feelings of fear?	1	2	3	4
27c.	Do your pelvic or vaginal symptoms cause you to experience feelings of fear?	1	2	3	4

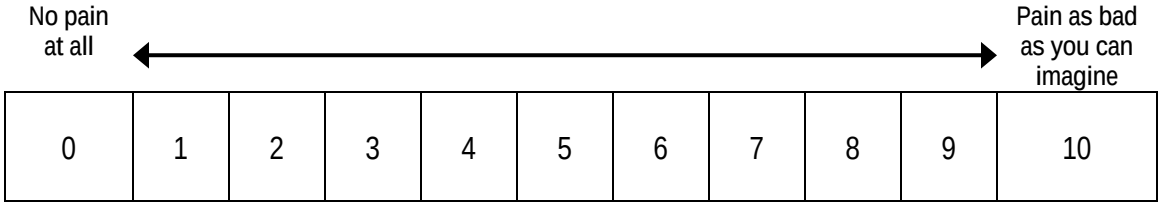
A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

		Not at all	Somewhat	Moderately	Quite a bit
28a.	Do your bladder or urine symptoms cause you to experience feelings of frustration?	1	2	3	4
28b.	Do your bowel or rectum symptoms cause you to experience feelings of frustration?	1	2	3	4
28c.	Do your pelvic or vaginal symptoms cause you to experience feelings of frustration?	1	2	3	4
29a.	Do your bladder or urine symptoms cause you to experience feelings of anger?	1	2	3	4
29b.	Do your bowel or rectum symptoms cause you to experience feelings of anger?	1	2	3	4
29c.	Do your pelvic or vaginal symptoms cause you to experience feelings of anger?	1	2	3	4
30a.	Do your bladder or urine symptoms cause you to experience feelings of depression?	1	2	3	4
30b.	Do your bowel or rectum symptoms cause you to experience feelings of depression?	1	2	3	4
30c.	Do your pelvic or vaginal symptoms cause you to experience feelings of depression?	1	2	3	4
31a.	Do your bladder or urine symptoms cause you to experience feelings of embarrassment?	1	2	3	4
31b.	Do your bowel or rectum symptoms cause you to experience feelings of embarrassment?	1	2	3	4
31c.	Do your pelvic or vaginal symptoms cause you to experience feelings of embarrassment?	1	2	3	4

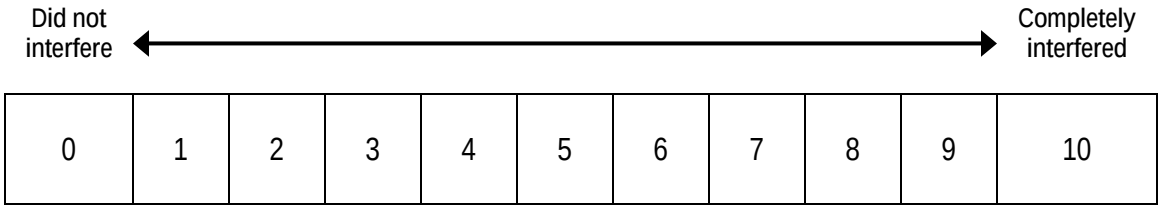
Thank you, we are now at the end of this section. I really appreciate your willingness to go through this questionnaire with me.

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

1. On average, over the last week, how much pain have you had in your abdominal or suprapubic area; how would you describe your pain on a scale from 0 to 10, where "0" is "no pain at all" and "10" is "pain as bad as you can imagine?"



2. (Ask if answer above is >0) On average, over the last week, how much did your pain in the abdominal or suprapubic area interfere with your doing your general activities; please describe this on a scale from 0 to 10 where "0" is "did not interfere" and "10" is "completely interfered?"



Adapted from "The Brief Pain Inventory" (Cleeland 1982)

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

The next set of items covers material that is sensitive and personal. Specifically, these questions ask about matters related to your sexual activity in the past 3 months. We realize that for some women, sexual activity is an important part of their lives; but for others it is not. To help us understand how your bladder and pelvic problems might affect your sexual activity, we would like you to answer the following questions from your own personal viewpoint.

Remember, your confidentiality is assured. While we hope you are willing to answer all of the questions, if there are any questions you would prefer not to answer, you are free to skip them. Please select the most appropriate response to each question. Remember these questions are only relevant to sexual activity in the past 3 months.

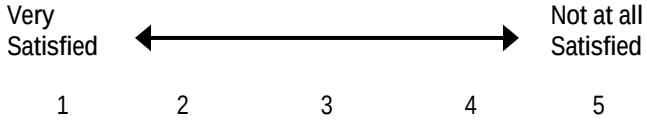
A1. In the past 3 months, have you engaged in sexual activities with a partner?

1	Yes → COMPLETE SECTION B BELOW
2	No → COMPLETE SECTION C (beginning on page 3)

SECTION B: FOR WOMEN WHO HAVE ENGAGED IN SEXUAL ACTIVITY WITH A PARTNER IN THE LAST 3 MONTHS

	Never	Seldom	Sometimes	Usually	Always
B1. How frequently do you feel sexual desire? This feeling may include wanting to have sex, planning to have sex, feeling frustrated due to lack of sex, etc.	1	2	3	4	5
B2. Do you climax (have an orgasm) when having sexual intercourse with your partner?	1	2	3	4	5
B3. Do you feel sexually excited (turned on) when having sexual activity with your partner?	1	2	3	4	5

B4. On a 5-point scale where "1" indicates very satisfied and "5" indicates not at all satisfied, how satisfied are you with the variety of sexual activities in your current sex life?



A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

	Never	Seldom	Sometimes	Usually	Always
B5. Do you feel pain during sexual intercourse?	1	2	3	4	5
B6. Are you incontinent of urine (leak urine) with sexual activity?	1	2	3	4	5
B7. Does fear of incontinence (either urine or stool) restrict your sexual activity?	1	2	3	4	5
B8. Do you avoid sexual intercourse because of bulging in the vagina (either the bladder, rectum or vagina)?	1	2	3	4	5
B9. When you have sex with your partner, do you have negative emotional reactions such as fear, disgust, shame or guilt?	1	2	3	4	5

	Never	Seldom	Sometimes	Usually	Always	Not Applicable
B10. Does your partner have a problem with erections that affects your sexual activity?	1	2	3	4	5	6
B11. Does your partner have a problem with premature ejaculation that affects your sexual activity?	1	2	3	4	5	6

	Much more intense	More intense	Same intensity	Less intense	Much less intense
B12. Compared to orgasms you have had in the past, how intense are the orgasms you have had in the past six months?	1	2	3	4	5

Thank you. THIS COMPLETES THIS SECTION

SKIP SECTION C (the next page)

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

SECTION C: FOR WOMEN WHO REPORT NO SEXUAL ACTIVITY WITH A PARTNER IN THE LAST 3 MONTHS

	Yes	No
C1. Do you have a partner at this time?	1	2

	Never	Seldom	Sometimes	Usually	Always
C2. How frequently do you feel sexual desire? This feeling may include wanting to have sex, planning to have sex, feeling frustrated due to lack of sex, etc.	1	2	3	4	5

C3. On a 5-point scale where "1" indicates very satisfied and "5" indicates not at all satisfied, how satisfied are you with the variety of sexual activity in your current sex life?

Very Satisfied				Not at all Satisfied
1	2	3	4	5

	Never	Seldom	Sometimes	Usually	Always
C4. Does fear of pain during sexual intercourse restrict your activity?	1	2	3	4	5
C5. Does fear of incontinence (either stool or urine) during sexual intercourse restrict your sexual activity?	1	2	3	4	5
C6. Do you avoid sexual intercourse because of bulging in the vagina (either the bladder, rectum or vagina falling out)?	1	2	3	4	5

THIS COMPLETES SECTION C

PFDN **OPUS** Form 39 Adaptation Index

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A4. Visit: 1.☐ Baseline 2.☐ 3 mo 3. ☐ 6 mo 4.☐ 12 mo

Sometimes women with bladder, bowel, or pelvic problems use aids or make changes in their routine to help them carry out their daily activities. Please listen to each of these items and think about any changes or adjustments that you have made in your usual activities because of any pelvic prolapse, urinary incontinence, and/or fecal incontinence problems. In each case, thinking about yourself in general over the past week, please indicate the one response that best describes you and your situation.

Adaptation Item	Frequency					Impact [If frequency is not 'Never"] How much would you say having to do this bothers you?				
	1 Never	2 Rarely	3 Sometimes	4 Often	5 Always	1 Not at All	2 A Little	3 Some	4 Moderate Amount	5 A Lot
1 I use protective undergarments (sometimes called adult diapers, guards, or briefs).	1	2	3	4	5	1	2	3	4	5
2. I use sanitary napkins, panty liners, or pads.	1	2	3	4	5	1	2	3	4	5
3. I use products to control urine or bowel odor (such as perfume, powder, deodorant sprays, or douching).	1	2	3	4	5	1	2	3	4	5
4. Whenever I go out, I always know or locate the nearest restroom.	1	2	3	4	5	1	2	3	4	5
5. I wear certain kinds of clothes (such as dark-colored clothing or long coats or tops) because of my prolapse or incontinence problems.	1	2	3	4	5	1	2	3	4	5
6. I urinate whenever possible whether I need to or not.	1	2	3	4	5	1	2	3	4	5
7. I avoid standing for long periods of time because of my prolapse or incontinence problems.	1	2	3	4	5	1	2	3	4	5
8. I try to drink less fluids or limit my fluid intake.	1	2	3	4	5	1	2	3	4	5
9. I avoid caffeine or drink decaffeinated beverages because of my prolapse or incontinence problems.	1	2	3	4	5	1	2	3	4	5
10. I limit or avoid foods that might irritate my bowels or cause gas (such as fruit, spicy foods, etc).	1	2	3	4	5	1	2	3	4	5
11. I fast or avoid eating for several hours before events or before going out in public.	1	2	3	4	5	1	2	3	4	5

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date:___ ___/___ ___/___ ___ ___ ___
Month Day Year

Adaptation Item	Frequency					Impact [If frequency is not 'Never"] How much would you say having to do this bothers you?				
	1 Never	2 Rarely	3 Sometimes	4 Often	5 Always	1 Not at All	2 A Little	3 Some	4 Moderate Amount	5 A Lot
12. I bathe or shower more than once a day because of my prolapse or incontinence problems.	1	2	3	4	5	1	2	3	4	5
13. I limit or avoid travel in cars, planes, trains, and buses because of my prolapse or incontinence problems.	1	2	3	4	5	1	2	3	4	5
14. I limit or avoid social activities outside my own home because of my prolapse or incontinence problems (including hobbies and recreation, religious activities, concerts or plays).	1	2	3	4	5	1	2	3	4	5
15. I limit or avoid physical activities because of my prolapse or incontinence problems (including strenuous exercise, heavy lifting, or swimming).	1	2	3	4	5	1	2	3	4	5
16. I leave the house only during certain times of the day (for example, only after I have emptied my bladder or bowel).	1	2	3	4	5	1	2	3	4	5
17. I carry supplies or a "survival kit" to help clean up after myself (for example, spare underwear or clothing, washcloth, plastic bag for soiled garments, plastic gloves, finger cots, cleansing or baby wipes, tissue).	1	2	3	4	5	1	2	3	4	5
18. I do things on my own to hold my prolapse in (for example, wear a girdle or tight undergarments; insert a tampon or other item).	1	2	3	4	5	1	2	3	4	5
19. I avoid sitting for long periods of time because of my prolapse or incontinence problems.	1	2	3	4	5	1	2	3	4	5
20. I wear clothes that are easy to remove (e.g., loose-fitting, elastic waist, no zippers, or wear skirts instead of slacks).	1	2	3	4	5	1	2	3	4	5

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___ A2. Date:___ ___/___ ___/___ ___ ___ ___
Month Day Year

Adaptation Item	Frequency					Impact [If frequency is not 'Never"] How much would you say having to do this bothers you?				
	1 Never	2 Rarely	3 Sometimes	4 Often	5 Always	1 Not at All	2 A Little	3 Some	4 Moderate Amount	5 A Lot
21. I plan and schedule my daily activities around my prolapse or incontinence problems.	1	2	3	4	5	1	2	3	4	5
22. I deal with my prolapse or incontinence problems on my own without telling family and/or friends.	1	2	3	4	5	1	2	3	4	5
23. I deal with my prolapse or incontinence problems by choosing to tell family and/or friends.	1	2	3	4	5	1	2	3	4	5
24. Please answer the following question if you are sexually active: I limit or prepare especially for sexual activities because of my prolapse or incontinence problems.	1	2	3	4	5	1	2	3	4	5
25. Is there anything else you do yourself to adapt to or cope with your prolapse or incontinence problems?										
a. Describe:	1	2	3	4	5	1	2	3	4	5
b. Describe:	1	2	3	4	5	1	2	3	4	5

Thank you for your answers – they are very helpful to our study.

A1. Site/Study ID #: ___ ___ / ___ ___ ___ ___ ___

COMPLETE ONLY AT THE 12 MONTH VISIT

1. Have you found out or been told (by one of your doctors or nurses) if you had the additional study procedure at the time of your prolapse surgery?

1. ☐ Yes → a. Did you have the additional procedure? 1. ☐ Yes 2. ☐ No 3. ☐ Don't know

2. ☐ No → b. Do you think you had the additional procedure? 1. ☐ Yes 2. ☐ No 3. ☐ Don't know

C1. Inpatient Services Use Codes

102 Other Kidney & Urinary Tract Diagnoses
103 Female Reproductive System Reconstructive Procedures
104 Vagina, Cervix & Vulva Procedures
105 Uterine & Adnexa Procedure for Non-Malignancy
106 Urethral Procedures
107 Kidney and Ureter Procedures for Non-Neoplasm
108 Simple Pneumonia & Pleurisy
109 Pulmonary Embolism
110 Hernia Procedures Except Inguinal & Femoral
111 Gastrointestinal Obstruction
112 Gastrointestinal Hemorrhage
113 Kidney & Urinary Tract Infections
114 Infections, Female Reproductive system

C2. Outpatient Services Use Codes

Office Visits:

201 Post-op Follow Up Visit (a follow up visits that occurs within 90 days of surgery)
202 Research Study Visit (when clinical care is rendered at the time of the research visit beyond those tests or procedures done for research purposes only)
203 Office or Other Outpatient Visit for the Evaluation and Management of an ESTABLISHED Patient
204 Office or Other Outpatient Visit for the Evaluation and Management of a NEW Patient
206 Emergency Department Visit
207 Telephone Contact (related to a urologic or gynecologic condition or complications/problems related to the treatment of these conditions)

Deleted: 205 Office consultation for a new or established patient .

Diagnostic Tests for Radiology Services

301 Computed Tomography (CT), pelvis
302 Computed Tomography (CT), abdomen
303 Computed Tomography (CT), thorax
304 Chest x-ray
305 X-ray exam of abdomen
306 X-ray, urethra/bladder, voiding
307 X-ray exam of small intestine
308 Contrast x-ray, urinary tract
309 Ultrasound exam (non-obstetric), pelvic
310 Ultrasound exam, abdominal
311 Ultrasound exam, retroperitoneal (abdominal back wall, e.g., renal, aorta, nodes)
312 Ultrasound exam, transvaginal (non-obstetric)
313 Echocardiographic exam of heart
314 Echocardiography, transthoracic
315 Doppler echocardiography color flow (used in addition to echocardiography)
316 Doppler echo exam, heart
317 MRI, pelvis

318 Perfusion lung image
319 Extremity venous study
320 Anorectal manometry

Lab Tests

401 Urinalysis, non automated with microscope
402 Urinalysis, Automated, with microsopy
403 Urinalysis, Non-automated, without microscopy
404 Urinalysis, Automated, without microscopy
405 Microscopic exam of urine
406 Urine bacteria culture
407 Microbiology, susceptibility studies, disk method
408 Culture, bacterial; blood
409 Culture, bacterial; stool
410 Culture, bacterial; any other source except urine, blood or stool

Urodynamics

501 Simple cystometrogram (CMG) (e.g., spinal manometer)
502 Complex cystometrogram (e.g., calibrated electronic equipment)
503 Simple uroflowmetry (UFR) (e.g., stop-watch flow rate, mechanical uroglowmeter)
504 Complex uroflowmetry (e.g., balibrated electronic equipment)
505 Electromyography studies (EMG) of anal or urethral sphincter, other than needle, any technique
506 Urine voiding pressure study (VP); bladder voiding pressure, any technique
507 Ultrasound measurement of post-voiding residual urine and/or bladder capacity, non-imaging
508 Intra-abdominal voiding pressure test (AP) (rectal, gastric, intraperitoneal)

Surgery

601 Sling operation for stress incontinence (e.g., fascia or synthetic)
602 Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy
603 Colpopexy, intraperitoneal approach (uterosacral, levator myorrhaphy)
604 Colpopexy, vaginal; extra-peritoneal apporach (sacrospinous, iliococcygeus)
605 Removal or revision of sling for stress incontinence (e.g., fascia or synthetic)
606 Laparoscopy, surgical, colpopexy (suspension of vaginal apex)
607 Vaginal hysterectomy; with removal of tube(s), and/or ovary(s), with repair of enterocele
608 Laparoscopy, surgical; with lysis of adhesions (salpingolysis, ovariolysis)
609 Repair of rectocele
610 Cystourethrascopy, with fulguration (including cryosurgery or laser surgery) or treatment of minor lesion(s) with or without biopsy
611 Cystourethrascopy, with removal of foreign body, calculus, or uretheral stent from urethra or bladder
612 Urethrolysis, transvaginal, secondary, open (e.g., postsurgical obstruction, scarring) (including cystourethroscopy, do not report cystourethroscopy simultaneously)
613 Hysteroscopy, with endometrial ablation (e.g., endometrial resection, electrosurgical ablation, thermoablation)
614 Mesh erosion repair

Drug/Durable Medical Equipment/prosthetics and orthotics/parenteral and enteral nutrition/surgical dressings/therapeutic shoes and inserts

701 Botulinum Toxin A, per unit
702 Pessary, any type

Other

801 Routine venipuncture (blood draw)
802 Initial hospital care, for the evaluation and management of a patient
803 Subsequent hospital care, for the evaluation and management of a patient
804 Injection procedure for cystography or voiding urethrocystography (bladder X-ray)
805 Insertion of non-indwelling bladder catheter (e.g., straight catheterization for residual urine) by a health care provider
806 Insertion of temporary indwelling bladder catheter (e.g., Foley) by a health care provider
807 Fitting and insertion of pessary or other intravaginal support device
808 Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
809 Cystourethroscopy
810 Cystourethroscopy with ureteral catheterization
811 Colposcopy of the vulva, with biopsy(s)
812 Colposcopy of the entire vagina, with cervix if present, without biopsy(s)
813 Conization of cervix
814 Biopsy of vulva or perineum
*815 Biofeedback training, perineal muscles, anorectal or urethral sphincter
816 Exploration, retroperitoneal area with or without biopsy(s)
817 Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise
818 Insert emergency airway
819 Electrocardiographic (ECG) monitoring for 24 hours
820 Electrocardiogram, routine ECG
*821 Physical therapy evaluation
*822 Physical therapy re-evaluation
*823 Therapeutic exercise/activities (physical therapy), direct (one-on-one) patient contact
*824 Group therapeutic procedure(s) (physical therapy), 2 or more individuals
*825 Electrical stimulation (attended)
*826 Electrical stimulation (unattended)
*827 Neuromuscular reeducation
828 Removal of bladder catheter, simple
829 Removal of bladder catheter, complicated
507 Ultrasound measurement of post-voiding residual urine and/or bladder capacity, non-imaging

C3. Nursing Home or Relevant Home Health Services Use Codes

001 Skilled Nursing Care
002 Physical Therapy
003 Speech Therapy/Speech-Language Pathology
004 Occupational Therapy

005 Medical Social Services (help persons or families cope with the social, psychological, cultural and medical issues resulting from an illness, e.g., counsel patients, explain health-care resources and policies, help plan for post-hospital patient needs by arranging for services at another facility or in the home.)
006 Home Health Aide Services (provide personal services such as bathing, dressing, toileting, making meals, light cleaning and transporting patients to the doctor)
007 Custodial or Supportive Care (typically provided by companion/homemakers to help with chores around the house but usually do not perform personal duties for the care recipient)

* When physical therapy, biofeedback, neuromuscular reeducation, or electrical stimulation treatment involves multiple visits, each visit should be reported separately on Form 17 with the appropriate C2 codes characterizing the visit. For example, if a subject reports 4 physical therapy visits on date May 9, May 13, May 15, and May 20 respectively, each of these visits should be reported using a separate row in Table C2 with the corresponding diagnosis information (or reason for visit), C2 code(s), date of visit, “Relevance” check box, clinical site, travel distance, and work loss.