TOMUS

F307
BASELINE PATIENT SURVEY

**The UITN is supported by cooperative agreements from
the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
in collaboration with
the National Institute of Child Health and Human Development (NICHD)**

F307: BASELINE PATIENT SURVEY, version 03/27/06 (A)_rev05/16/06

SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY:

A1. STUDY ID#: LABEL

A2. VISIT # BASELINE .....TBAS

A3. DATE FORM DISTRIBUTED: ___ ___ / ___ ___ / ___ ___ ___ ___
MONTH DAY YEAR

A4. STUDY STAFF INITIALS: ____ ____ ____

A5. MODE: SELF-ADMINISTERED 1
INTERVIEWER-ADMINISTERED..... 2

A6. WHICH VERSION OF THIS FORM WAS USED? ENGLISH..... 1
SPANISH 2

A7. IS THIS A REPEAT MEASURE? YES 1
NO..... 2

Affix ID Label Here

Introduction: Thank you for agreeing to participate in the TOMUS study.

We will ask you to complete a survey like this one at several time points in the study. This survey is called the Baseline Patient Survey and is completed at a pre-surgical study visit. The survey contains questions about your expectations of the surgery, and measures of your current urinary symptoms, your quality of life, your capabilities to perform routine daily living activities, and sexual activities.

As with all of the information we collect for this research study, all of your responses are completely confidential. Your responses are never linked with your name and your name never appears on any of the research documents. Providing this information will not affect any of your services, benefits, or eligibility for coverage.

This survey should take about 15 minutes to complete. Ideally, you will be able to complete the entire survey in one sitting.

There are five (5) parts to the Baseline Patient Survey. Please read the instructions at the start of each section carefully before you begin each new section.

Try to answer every item, but do not dwell too long on any one question. We want your answers, so please complete the questionnaire on your own. After you have completed the Survey, please check to make sure you have not missed any items. If you have any questions about any of these items, please call me:

_____ at _____.

A8. What is the date that you are starting to fill out this Survey? ____ ___ / ____ ____ / ____ ____ ____ ____
Month Day Year

Affix ID Label Here

Section B: Expectations of Surgery

Women with urinary incontinence can be bothered by symptoms such as urine leakage, urgency to urinate, frequent urination, etc. It is also common for women to alter their lifestyle, limit social and physical activities, or feel certain emotions because of urinary incontinence. These questions ask you to tell us what expectations you have for symptom relief **after** you recover from your upcoming bladder surgery. This will help us to understand how you think that surgery will improve your symptoms, lifestyle, and/or emotions.

GENERAL INSTRUCTIONS: Please read the first column of each section and indicate a **"Yes" or "No"** answer to each question by circling **1** (Yes) or **2** (No). Then, for each question marked by a **"Yes"** answer, work across the page and tell us about what you expect to happen **after you recover from surgery.** Circle the one response that **best** describes your expectation.

This first section asks about **symptoms** that you might currently experience because of your bladder problem.

Do you currently experience any of the following symptoms?			**IF YES,** Circle the one response below that best describes how much better you expect this symptom to be after you recover from surgery.				
	Yes	**No**	**No Better**	**Slightly better**	**Somewhat better**	**Much better**	**Completely better**
B1. Urine leakage	Yes 1	No 2	1	2	3	4	5
B2. An urgency to urinate such that you fear not making it to the bathroom in time	Yes 1	No 2	1	2	3	4	5
B3. Frequent urination	Yes 1	No 2	1	2	3	4	5
B4. Any other symptoms? _____ (If yes, specify symptom)	Yes 1	No 2	1	2	3	4	5

Affix ID Label Here

This next section asks about **activities** that you might currently limit because of your bladder problems.

Do you currently limit any of the following activities because of your bladder problems?			**IF YES**, circle the one response that best describes how much more capable you expect to be able to perform this activity after you recover from surgery.				
	Yes	**No**	**No more capable**	**Slightly more capable**	**Somewhat more capable**	**Much more capable**	**Completely capable**
B5. Physical activities (e.g. housework, yardwork, going for a walk, dancing, jogging, golfing)	Yes 1	No 2	1	2	3	4	5
B6. Social activities (e.g. visiting friends, vacationing, going to church or temple).	Yes 1	No 2	1	2	3	4	5
B7. Sexual activity	Yes 1	No 2	1	2	3	4	5
B8. Any other activities? _____ (If yes, describe activity)	Yes 1	No 2	1	2	3	4	5

This section asks about **emotions** that you might currently experience because of your bladder problems.

			IF YES, circle the one response that best describes how much less you expect to be bothered by your emotions after you recover from surgery.				
B9. Are you bothered by feelings of embarrassment, helplessness, frustration, and/or depression because of your bladder problems?	Yes 1	No 2	**No less bothered** 1	**Slightly less bothered** 2	**Somewhat less bothered** 3	**Much less bothered** 4	**Completely not bothered** 5

B10. Of all the symptoms, lifestyle restrictions or emotions that you experience because of your bladder problems, which one problem do you expect to improve the most after you recover from surgery?

_____

Affix ID Label Here

Section C: Urinary Symptoms

	Normal	Mild	Moderate	Severe
C1. Circle the one number that best describes how your urinary tract condition is now.	1	2	3	4

	Never	About once a week or less often	Two or three times a week	About once a day	Several times a day	All the time
C2. How often do you leak urine?	0	1	2	3	4	5

	None	A small amount	A moderate amount	A large amount
C3. We would like to know how much urine you think leaks. How much urine do you usually leak whether you wear protection or not?	0	1	2	3

C4. Overall, how much does leaking interfere with your everyday life? Draw a single vertical line at the point on this line from "not at all" to "a great deal" that represents how much leaking interferes with your daily life.

(not at all) **(a great deal)**

C4 Code

Please tell us when urine leaks. Circle YES for all that apply to you and NO for those that do not.

	Yes	No
C5. Never – urine does not leak	Yes 1	No 2
C6. Leaks before you can get to the toilet	Yes 1	No 2
C7. Leaks when you cough or sneeze	Yes 1	No 2
C8. Leaks when you are asleep	Yes 1	No 2
C9. Leaks when you are physically active/exercising	Yes 1	No 2
C10. Leaks when you have finished urinating and are dressed	Yes 1	No 2
C11. Leaks for no obvious reason	Yes 1	No 2
C12. Leaks all the time	Yes 1	No 2

Section D: Quality of Life, Part II

These questions deal specifically with your accidental urine loss and/or prolapse. The symptoms in this section have been described by women who experience accidental urine loss and/or prolapse. Please indicate which symptoms you are now experiencing, and how bothersome they are for you. Be sure to circle an answer for all items.

GENERAL INSTRUCTIONS: Please read the first column of symptoms and circle "Yes" or "No" for each symptom. Then, for each question marked by a **"Yes"** answer, work across the page and tell us how bothersome that symptom is for you currently.

Do you currently experience …..			**IF YES,** Circle the one response below that best describes how bothersome that symptom is for you.			
	Yes	**No**	**Not at all bothersome**	**Slightly bothersome**	**Moderately bothersome**	**Greatly bothersome**
D1. …frequent urination?	Yes 1	No 2	0	1	2	3
D2. …a strong feeling of urgency to empty your bladder?	Yes 1	No 2	0	1	2	3
D3. …urine leakage related to the feeling of urgency?	Yes 1	No 2	0	1	2	3
D4. …urine leakage related to physical activity, coughing or sneezing?	Yes 1	No 2	0	1	2	3
D5. ..general urine leakage **not** related to urgency or activity?	Yes 1	No 2	0	1	2	3
D6. …small amounts of urine leakage (that is, drops)?	Yes 1	No 2	0	1	2	3
D7. …large amounts of urine leakage?	Yes 1	No 2	0	1	2	3
D8. …nighttime urination?	Yes 1	No 2	0	1	2	3

Affix ID Label Here

Do you currently experience …..	Yes	No	IF YES, Circle the one response below that best describes how bothersome that symptom is for you. Not at all bothersome	Slightly bothersome	Moderately bothersome	Greatly bothersome
D9. …bedwetting?	Yes 1	No 2	0	1	2	3
D10. …difficulty emptying your bladder?	Yes 1	No 2	0	1	2	3
D11. …a feeling of incomplete bladder emptying?	Yes 1	No 2	0	1	2	3
D12. …lower abdominal pressure?	Yes 1	No 2	0	1	2	3
D13. …pain when urinating?	Yes 1	No 2	0	1	2	3
D14. …pain in the lower abdominal or genital area?	Yes 1	No 2	0	1	2	3
D15. …heaviness or dullness in the pelvic area?	Yes 1	No 2	0	1	2	3
D16. …a feeling of bulging or protrusion in the vaginal area?	Yes 1	No 2	0	1	2	3
D17. ...bulging or protrusion you can see in the vaginal area?	Yes 1	No 2	0	1	2	3
D18. ...pelvic discomfort when standing or physically exerting yourself?	Yes 1	No 2	0	1	2	3
D19. Do you have to push on the vagina or perineum to empty your bladder?	Yes 1	No 2	0	1	2	3
D20. Do you have to push on the vagina or perineum to have a bowel movement?	Yes 1	No 2	0	1	2	3

Affix ID Label Here

D21. Do you experience any **other** symptoms related to accidental urine loss or prolapse? YES 1

NO..... 2 ➔ **SKIP TO D22**

D21a. If yes, what is it (are they)? _____

D22. Please go back and review all of the symptoms in Section D above, items D1 – 21, and write below the one symptom that bothers you the most. For this item, please list **one** symptom only.

_____ ☐

_____

Some women find that accidental urine loss and/or prolapse may affect their activities, relationships, and feelings. The questions in this section refer to areas in your life which may have been influenced or changed by your problem. For each question in this section, circle the one response that best describes how much your activities, relationships and feelings are being affected by urine leakage and/or prolapse.

To what extent has accidental urine loss and/or prolapse affected your …..

	Not at all	**Slightly**	**Moderately**	**Greatly**
D23. …ability to do household chores (cooking, housecleaning, laundry)?	0	1	2	3
D24. …ability to do usual maintenance or repair work done in home or yard?	0	1	2	3
D25. …shopping activities?	0	1	2	3
D26. …hobbies and pastime activities?	0	1	2	3
D27. …physical recreational activities such as walking, swimming, or other exercise?	0	1	2	3
D28. …entertainment activities such as going to a movie or concert?	0	1	2	3

To what extent has accidental urine loss and/or prolapse affected your …..

	Not at all	Slightly	Moderately	Greatly
D29. …ability to travel by car or bus for distances less than 20 minutes away from home?	0	1	2	3
D30. …ability to travel by car or bus for distances greater than 20 minutes away from home?	0	1	2	3
D31. …going to places if you are not sure about available restrooms?	0	1	2	3
D32. …going on vacation?	0	1	2	3
D33. …church or temple attendance?	0	1	2	3
D34. …volunteer activities?	0	1	2	3
D35. …employment (work) outside the home?	0	1	2	3
D36. …having friends visit you in your home?	0	1	2	3
D37. …participation in social activities outside your home?	0	1	2	3
D38. …relationship with friends?	0	1	2	3
D39. …relationship with family excluding husband/companion?	0	1	2	3
D40. …ability to have sexual relations?	0	1	2	3
D41. …the way you dress?	0	1	2	3
D42. …emotional health?	0	1	2	3

To what extent has accidental urine loss and/or prolapse affected your …..

	Not at all	Slightly	Moderately	Greatly
D43. …physical health?	0	1	2	3
D44. …sleep?	0	1	2	3
D45. How much does fear of odor restrict your activities?	0	1	2	3
D46. How much does fear of embarrassment restrict your activities?	0	1	2	3

In addition, does your problem with accidental urine loss and/or prolapse cause you to experience ….

	Not at all	Slightly	Moderately	Greatly
D47. …nervousness or anxiety?	0	1	2	3
D48. …fear?	0	1	2	3
D49. …frustration?	0	1	2	3
D50. …anger?	0	1	2	3
D51. …depression?	0	1	2	3
D52. …embarrassment?	0	1	2	3

Affix ID Label Here

Over the last 2 weeks, how often have you been bothered by any of the following problems? Please circle the number that indicates how often you have been bothered by each problem.

	Not at all	Several days	More than half the days	Nearly every day
E14. Little interest or pleasure in doing things	0	1	2	3
E15. Feeling down, depressed, or hopeless	0	1	2	3
E16. Trouble falling asleep or staying asleep, or sleeping too much	0	1	2	3
E17. Feeling tired or having little energy	0	1	2	3
E18. Poor appetite or overeating	0	1	2	3
E19. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
E20. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
E21. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
E22. Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3

E23. If you circled 1, 2 or 3 for any of the above problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all 1

Somewhat difficult 2

Very difficult 3

Extremely difficult 4

Section F: Sexual Activities

This section covers material that is sensitive and personal. Specifically, these questions ask about matters related to your sexual activity **in the past 6 months**. For some women, sexual activity is an important part of their lives; but for others it is not. Everyone has different ideas on the subject. To help us understand how your bladder problems might affect your sexual activity, we would like you to answer the following questions from your own personal viewpoint.

There are no right or wrong answers. Remember, your confidentiality is assured. While we hope you are willing to answer all of the questions, if there are questions you would prefer not to answer, you are free to skip them. Please select the most appropriate response to each question by circling the answer you choose. Remember these questions are only relevant to sexual activity **in the past six months**.

F1. **In the past 6 months**, have you engaged in sexual activities with a partner?

Yes ..... 1 ➔**COMPLETE SECTION G BELOW**

No..... 2 ➔**SKIP TO PAGE 16 AND COMPLETE SECTION H**

Section G: FOR WOMEN WHO HAVE ENGAGED IN SEXUAL ACTIVITY WITH A PARTNER IN THE LAST 6 MONTHS

G1. 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.

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

G2. Do you climax (have an orgasm) when having sexual intercourse with your partner?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

G3. Do you feel sexually excited (turned on) when having sexual activity with your partner?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

G4. How satisfied are you with the variety of sexual activities in your current sex life?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

G5. Do you feel pain during sexual intercourse?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

G6. Are you incontinent of urine (leak urine) with sexual activity?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

G7. Does fear of incontinence (either urine or stool) restrict your sexual activity?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

G8. Do you avoid sexual intercourse because of bulging in the vagina (either the bladder, rectum or vagina falling out)?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

G9. When you have sex with your partner, do you have negative emotional reactions such as fear, disgust, shame or guilt?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

G10. Does your partner have a problem with <u>erections</u> that affects your sexual activity?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

G11. Does your partner have a problem with <u>premature ejaculation</u> that affects your sexual activity?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

G12. Compared to orgasms you have had in the past, how intense are the orgasms you have had in the past 6 months?

Much less intense	Less intense	Same intensity	More intense	Much more intense
1	2	3	4	5

YOU ARE DONE WITH THIS QUESTIONNAIRE. THANK YOU.

Section H: FOR WOMEN WHO REPORT NO SEXUAL ACTIVITY WITH A PARTNER IN THE LAST 6 MONTHS

H1. Do you have a partner at this time?

Yes 1

No 2

H2. 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.

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

H3. How satisfied are you with the variety of sexual activities in your current sex life?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

H4. Does fear of pain during sexual intercourse restrict your activity?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

H5. Does fear of incontinence (either stool or urine) during sexual intercourse restrict your sexual activity?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

H6. Do you avoid sexual intercourse because of bulging in the vagina (either the bladder, rectum or vagina falling out)?

Always	Usually	Sometimes	Seldom	Never
1	2	3	4	5

YOU ARE DONE WITH THIS QUESTIONNAIRE. THANK YOU.