F381: Treatment Prior to Early Termination, version 07/19/07 (B)

UITN
TOMUS

Section A: General Study Information for Office Use Only:

A1. Study ID#: Label

A2. Date Form Completed: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

A3. Initials of Person Completing this Form: ____ ____ ____

A4. Patient's Last Study Visit: ___ ___ ___ ___

SECTION B: Patient Symptoms and Treatments

B1. Based upon a review of all source documents …

Since the last study visit for which data was collected, did the patient receive any new or continuing treatment for **voiding dysfunction**?

[*Voiding dysfunction is defined as using a catheter to facilitate bladder emptying OR is undergoing medical or surgical therapy to facilitate bladder emptying.]*

Yes..... 1 No..... 2➔ **SKIP TO B2**

TX_VOID_DYS	Frequency	Percent	Cum Freq	Cum Percent
.	586	.	.	.
2	11	100.00	11	100.00

B1a. Circle yes or no for all treatments received by the patient for **voiding dysfunction** since the last study visit:		**YES**	**NO**
i.	Any catheter use.....	1	2
ii.	Urethral dilation.....	1↓	2
	a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)		
iii.	Tape loosening.....	1↓	2
	a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)		
iv.	Tape incision.....	1↓	2
	a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)		
v.	Urethrolysis and tape take-down.....	1↓	2
	a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)		
vi.	Medication	1	2
vii.	Other	1↓	2
	a. Specify: _____		
	b. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)		

B1b. What was the date of the <u>first treatment of any kind</u> for **voiding dysfunction** since the patient's TOMUS surgery?

___ ___ / ___ ___ /___ ___ ___ ___
Month Day Year

B2. Based upon a review of all source documents…

<u>Since the last study visit for which data was collected</u>, is there new or continuing <u>evidence</u> of **vaginal prolapse**?

Yes..... 1 No 2

EVD_PROLAPSE	Frequency	Percent	Cum Freq	Cum Percent
.	586	.	.	.
1	5	45.45	5	45.45
2	6	54.55	11	100.00

B2a. Did the patient receive any new or continuing <u>treatment</u> for **vaginal prolapse** since the last study visit?

Yes..... 1 No ..... 2➔ **SKIP TO B3**

PRO_TREAT	Frequency	Percent	Cum Freq	Cum Percent
.	586	.	.	.
2	11	100.00	11	100.00

B2b. Circle yes or no for all <u>treatments received</u> by the patient for **vaginal prolapse** since the last study visit:	**YES**	**NO**
i. Anterior repair.....	1🡻	2
a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)		
ii. Posterior repair.....	1🡻	2
a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)		
iii. Enterocele repair	1🡻	2
a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)		
iv. Vaginal vault suspension	1🡻	2
a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)		
v. Pessary	1🡻	2
a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)		
vi. Other	1🡻	2
a. Specify: _____		
b. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)		

B2c. What was the date of the <u>first treatment of any kind</u> for **vaginal prolapse** since the patient's TOMUS surgery?

___ ___ / ___ ___ /___ ___ ___ ___
Month Day Year

B3. Based upon a review of all source documents…

<u>Since the last study visit for which data was collected</u>, is there evidence of new or continuing **urge incontinence**?

Yes ..... 1 No ..... 2 ➔**SKIP TO B4**

EVD_URGE	Frequency	Percent	Cum Freq	Cum Percent
.	586	.	.	.
1	10	90.91	10	90.91
2	1	9.09	11	100.00

B3a. Did the patient have **urge incontinence symptoms** prior to TOMUS surgery? **(REVIEW SECTION D ON F301)**

Yes (meets definition of persistent urge UI)..... 1 ➔**SKIP TO B4**

No 2

URGSYM_PRE	Frequency	Percent	Cum Freq	Cum Percent
.	586	.	.	.
-2	1	9.09	1	9.09
1	10	90.91	11	100.00

B3b. Did the patient receive any **treatment for urge incontinence** prior to TOMUS surgery? **(REVIEW QUESTION C9 ON F302 AND QUESTION B2 ON F303)**

Yes (meets definition of persistent urge UI)..... 1

No (meets definition of de novo urge UI)..... 2

B4. Did the patient receive any new or continuing <u>treatment</u> for **urge incontinence** since the last study visit?

Yes..... 1 No ..... 2➔ **SKIP TO B5**

TXURGE_IVIS	Frequency	Percent	Cum Freq	Cum Percent
.	586	.	.	.
1	11	100.00	11	100.00

B4a. Circle yes or no for all <u>treatments received</u> by the patient for **urge incontinence** since the last study visit:

	YES	**NO**

i. Medication 1 2

URGE_MED	Frequency	Percent	Cum Freq	Cum Percent
.	586	.	.	.
1	11	100.00	11	100.00

ii. Pelvic Muscle Rehabilitation ..... 1↓ 2

a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

iii. Behavioral Training ..... 1↓ 2

a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

iv. Biofeedback ..... 1↓ 2

a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

v. Other ..... 1↓ 2

a. Specify: _____

b. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

B4b. What was the date of the <u>first treatment of any kind</u> for **urge incontinence** since the patient's TOMUS surgery?

___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Analysis Variable : tx_days (date since randomization)								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
11	0	170.5	119.6	43.0	83.0	125.0	286.0	396.0

B5. Based upon a review of all source documents….

<u>Since the last study visit for which data was collected</u>, is there new or continuing <u>evidence</u> of **recurrent stress urinary incontinence (SUI)**?

Yes ..... 1 No 2

B5a. Did the patient receive any new or continuing <u>treatment</u> for **recurrent SUI** since the last study visit?

YES ..... 1 ➔ **TREATMENT FAILURE: COMPLETE FAILURE PROTOCOL**

NO ..... 2 ➔ **SKIP TO SECTION C**

B5b. Circle yes or no for all <u>treatments received</u> by the patient for **recurrent SUI** since the last study visit:

	YES	**NO**

i. Burch colposuspension ..... 1↓ 2

a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

ii. Sling procedure ..... 1↓ 2

a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

iii. Tightening of previous sling..... 1↓ 2

a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Additional dates: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

iv. Needle suspension (Raz, Pereyra, Stamey, Gittes, etc.)…….. ..... 1↓ 2

a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Additional dates: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

v. Suburethral plication …….. ..... 1↓ 2

a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Additional dates: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

vi. Periurethral bulking agent injection ……..... 1↓ 2

a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Additional dates: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

vii. Other surgical treatment …….. ..... 1↓ 2

a. Specify: _____

b. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Additional dates: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

viii. Alpha-agonists …….. ..... 1↓ 2

a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

ix. Other pharmacologic treatment ..... 1↓ 2

a. Specify: _____

b. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

x. Pelvic muscle rehabilitation (with or without biofeedback) ..... 1↓ 2

a. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

xi. Device insertion, such as vaginal cone, pessary, urethral plug, patch ..... 1 ↓ 2

a. Specify: _____

b. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Additional dates: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

xii. Any other treatment ..... 1 ↓ 2

a. Specify: _____

b. Specify date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

B5c. What was the date of the first treatment of any kind for **recurrent SUI**? _____ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

SECTION C: SURGEON'S SIGNATURE

Surgeon's Signature: _____ Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year