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

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**

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 first treatment of any kind for **voiding dysfunction** since the patient's TOMUS surgery?

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

Affix ID Label Here

B2. Based upon a review of all source documents…

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

Yes..... 1 No 2

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

Yes..... 1 No ..... 2➔ **SKIP TO B3**

B2b. Circle yes or no for all treatments received 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 first treatment of any kind for **vaginal prolapse** since the patient's TOMUS surgery?

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

Affix ID Label Here

B3. Based upon a review of all source documents…

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

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

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

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 treatment for **urge incontinence** since the last study visit?

Yes..... 1 No ..... 2➔ **SKIP TO B5**

B4a. Circle yes or no for all treatments received by the patient for **urge incontinence** since the last study visit:	**YES**	**NO**
i. Medication.....	1	2
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 first treatment of any kind for **urge incontinence** since the patient's TOMUS surgery?

___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

Affix ID Label Here

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

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

Yes..... 1 No 2

B5a. Did the patient receive any new or continuing treatment 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 treatments received 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 <u>first treatment of any kind</u> for **recurrent SUI**? ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

SECTION C: SURGEON'S SIGNATURE

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