F352: Follow-Up Physician Assessment, version 07/19/07 (C)



Section A: General Study Information for Office Use Only:						
A1. Study ID#:	Label		A2.	Visit #	F/U 6 Months	TF06
					F/U 12 Months	TF12
					F/U 24 Months	TF24
					Failure	TFAI
A3. Date Form Co	mpleted:/ Month Day	/	A4. 1	Initials of Pe		nis Form: Certified Surgeon Investigator

SECTION B: Patient Symptoms and Treatments

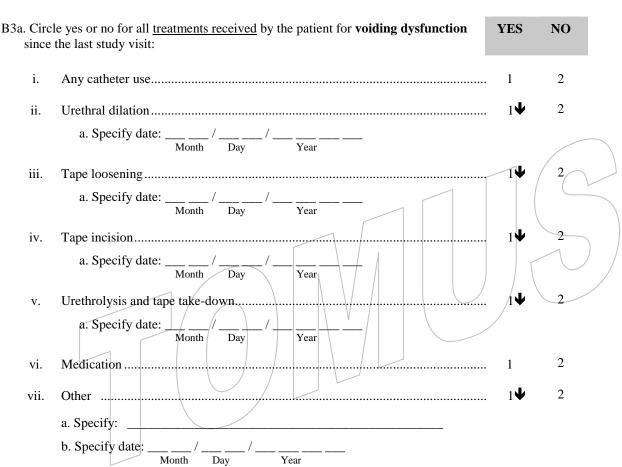
Dia t	ne patient report any pain ? (R	EVIEW BUON F328 FOR T	(HIS VISIT)
	Yes 1	No	2→ SKIP TO B2
B1a.	Do you judge this pain to be related to the patient	's TOMUS surgery?	
	Yes	1	
	No	2	
	Indeterminable		
Did tl	ne patient receive any new or continuing treatment	for this pain since the last stud	y visit?
	Yes 1	No	2 → SKIP TO B3
B2a.	Medication? Yes 1 No	2 →SKIP TO B2b	
	Circle yes or no for all medications listed:	YES N	О
	i. Non-steroidal and aspirin	1 2	2
	ii. Narcotics	1 2	2
	iii. Trigger point injections	1 2	2
	iv. Other	1 🗸	2
	Specify:		
B2b.	Physical Therapy? Yes	1 No 2	
B2c.	Other treatment or referrals? Yes	1 No	SKIP TO B3
	B2ci. Describe:		
	B1a. Did th B2a.	Yes	Yes

B3.	Based upon	a review	of all source	e documents	and Data Forms	

Did the patient receive any new or continuing treatment for voiding dysfunction since the last study visit?

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

Yes	1 No	2 ->	SKIP	TO	B4
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B3b. 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	

B4.	Racad upon	a raviaw	of all	COURCA	documente	and	Data Forms	
D4.	Dased upon	areview	or an	source	documents	anu	Data Forms	

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

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

YES NO

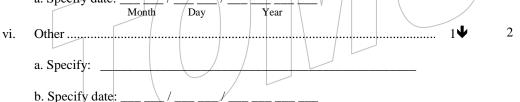
a. Specify date: ____ / ___ / ___ _ Year ____

a. Specify date: ____ / ___ / ___ Year _____

a. Specify date: ____ / ___ / ___ / ___ Vear

v. Pessary ____ / ___ / ___ / ___ 2

a. Specify date: ____ / ___ / ___ / ___ Year





B4b. 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

iv.

	Yes
B5a.	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 B6
	No
B5b.	Did the patient receive any treatment for urge incontinence prior to TOMUS surgery? (REVIEW QUESTION C9 ON AND QUESTION B2 ON F30)
	Yes (meets definition of persistent urge UI) 1
	No (meets definition of de novo urge UI)
B6.	Did the patient receive any new or continuing treatment for urge incontinence since the last study visit?
	Yes
	B6a. Circle yes or no for all <u>treatments received</u> by the patient for urge incontinence since the last study visit:
	i. Medication 1 2
	ii. Pelvic Muscle Rehabilitation
	a. Specify date://
	iii. Behavioral Training 1♥ 2
	a. Specify date://
	iv. Biofeedback
	a. Specify date: / / Year
	Month Day Year v. Other
	a. Specify:
	b. Specify date:/

B7. Based upon	a review of all sourc	e documents and	Data Forms
Is there new	v or continuing eviden	nce of recurrent	stress urinary incontinence (SUI) since the last study visit?
Yes.		1	No 2
B7a. Did th	ne patient receive any	new or continuir	ng treatment for recurrent SUI since the last study visit?
	YES	1 → TRE	EATMENT FAILURE: COMPLETE FAILURE PROTOCOL
	NO	2 → SKII	P TO SECTION C
	Circle yes or no for all since the last study vi		ved by the patient for recurrent SUI YES NO
i.	Burch colposusper	nsion	1 \P
	a. Specify date:	//	/
ii.		•	1 2
	a. Specify date:	//	Year
iii.			
	a. Specify date:		
ſ	Additional dates:	Month Day	Year
	Additional dates.	Month Day	Year
ı		Month Day	Year
iv.	Needle suspension	n (Raz, Pereyra, S	Stamey, Gittes, etc.)
	a. Specify date:	Month Day	/ <u>Year</u>
	Additional dates:	/	_/
		Month Day	Year
		Month Day	Year
v.			
	a. Specify date:	Month Day	/ <u></u>
	Additional dates:	/ Month Day	/
		•	_/
:	Dominanthual bullia	Month Day	Year
VI.			1 1 ♥ 2
		•	
	Additional dates:	Month Day	_/ <u></u>
		/	_/
		Month Day	Year

vii.	Other surgical treatment		1♥	2
	a. Specify:			
	b. Specify date://			
	Month Day Year			
	Additional dates: / / / Year			
	Month Day Year			
viii.	Alpha-agonists		1 ↓	2
	a. Specify date:// Year			
ix.	Other pharmacologic treatment		1 ↓	2
	a. Specify:			
	b. Specify date: / / Year			
х.	Pelvic muscle rehabilitation (with or without biofeedback)	<u> </u>	1	2
•••	a. Specify date: / / Year			
xi.	Device insertion, such as vaginal cone, pessary, urethral plug, patch	<u> </u>	1₩	2
	a. Specify:			
	b. Specify date:///			
	Month Day Year			
	Additional dates://			
	Month Day Year			2
xii.	Any other treatment		1 ♥	2
	a. Specify:			
	b. Specify date: / / Year			
at w	vas the date of the <u>first treatment of any kind</u> for recurrent SUI ?		_/	/
		Month	Day	Year

B7c.

SECTION C: Adverse Events or Complications

SECTION C SHOULD BE COMPLETED AFTER ALL OTHER VISIT COMPONENTS.

	Vos	1 L	 2 A SKID TO SECTION D
C1.	Did any adverse events of since the last study visit	_	ing dysfunction, urge incontinence, or pain occur OF PAGE

	Event Number (Refer to Pt AE Log)	Event Code (Refer to Box Below)	If Event Code = 99, Specify
a.		→	
b.		→	
c.		→	
d.		→	
e.		→	
f.		—————————————————————————————————————	
g.			

REMINDER: COMPLETE SEPARATE FORM/F391 FOR EACH ADVERSE EVENT OR COMPLICATION LISTED

EVENT CODES REFERENCE FOR C1				
16 = Mesh Complication: Erosion	23 = Recurrent UTI			
17 = Mesh Complication: Exposure	24 = Fistula: Vesicovaginal			
18 = Surgical Site Infection: Superficial Incisional	25 = Fistula: Urethrovaginal			
19 = Surgical Site Infection: Deep Incisional	26 = Fistula: Enterovesical			
20 = Surgical Site Infection: Organ/Space	27 = Fistula: Rectovaginal			
	29=Granulation Tissue			
	99 = Other			

SECTION D: SURGEON'S SIGNATURE	
Surgeon's Signature:	Date: / / Year

ADVERSE EVENT DEFINITIONS

source: section H2.h of the protocol

- Mesh Complication: Vaginal, urethral, bladder; erosion (defined as after primary healing, into an organ or surrounding tissue); exposure (defined as mesh visualized through a prior incision area with or without an inflammatory reaction). No time limit for reporting.
- <u>Surgical Site Infection</u> (based on 1992 CDC definition): No time limit for reporting. One of the following criteria must be met:
 - Evidence of any of the following signs at the surgical incision site: purulent drainage, pain or tenderness, localized swelling, redness or heat.
 - Deliberate opening of the wound unless culture negative.
 - Evidence of infection on re-operation or imaging study.
 - Diagnosis of infection by physician, confirmed by study surgeon.

Surgical site infections will be subcategorized into the following types:

- 1. <u>Superficial Incisional</u>: Involves only the skin and subcutaneous tissues at the incision site(s).
- 2. <u>Deep Incisional</u>: Involves deep soft tissue (e.g. fascial and muscle layers) at the operative site(s).
- 3. Organ/space: Organs or spaces, other than the incision, that were opened or manipulated during the operative procedure (includes pelvic abscess, peritonitis).
- Recurrent UTI: Presumed UTI with treatment, ≥3 in 1 year AFTER 6 week visit. No time limit for reporting.
- <u>Fistula</u>: No time limit for reporting.
 - Vesicovaginal: connection between bladder and vagina resulting in passage of urine per vaginum
 - <u>Urethrovaginal</u>: connection between urethra and vagina resulting in passage of urine per vaginum
 - Enterovesical: connection between bladder and bowel, may be diagnosed by pneumaturia, charcoal study, or cystoscopy
 - <u>Rectovaginal</u>: connection between the rectum and the vagina resulting in the passage of stool per vaginum.

NOTE: Foreign body reaction in space of Retzius resulting in vaginal discharge or bleeding or granulation tissue in vagina is NOT a fistula.

- <u>Granulation Tissue</u>: At or beyond the 6 week visit, granulation at the TOMUS surgical site. (If at or beyond 6 weeks there is granulation at a concomitant surgery site, that should be reported as an "other" [code 99] adverse event.) No time limit for reporting.