

SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY

A1. Study ID#: A2. Visit # F/U 6 Months TF06 F/U 24 Months TF24
 F/U 12 Months TF12 Failure TFAI

VISIT	Frequency	Percent	Cum Freq	Cum Percent
TF06	538	35.28	538	35.28
TF12	524	34.36	1062	69.64
TF24	459	30.10	1521	99.74
TFAI	4	0.26	1525	100.00

SECTION B: STRESS TEST AND PRELIMINARY PVR

B1. Voided volume prior to the **empty bladder stress test (EBST)**: _____ mL

Analysis Variable : ST_VOID_VOL								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1478	0	189.9	163.3	0.0	75.0	150.0	250.0	950.0

ST_VOID_VOL	Frequency	Percent	Cum Freq	Cum Percent
.	47	100.00	47	100.00

B2. Outcome of EBST: Positive without reduction 1
 Positive with reduction 2
 Negative 3 → SKIP TO B3

EMPTY_ST	Frequency	Percent	Cum Freq	Cum Percent
.	6	.	.	.
1	34	2.24	34	2.24
3	1485	97.76	1519	100.00

Frequency Missing = 6

B2a. Was the empty bladder stress test positive ... YES NO

i. ...with Valsalva in dorsal lithotomy position?..... 1 2

EBST_VAL	Frequency	Percent	Cum Freq	Cum Percent
.	1491	.	.	.
1	19	55.88	19	55.88
2	15	44.12	34	100.00

Frequency Missing = 1491

ii. ...with cough in dorsal lithotomy position?..... 1 2

EBST_COUGH	Frequency	Percent	Cum Freq	Cum Percent
.	1492	.	.	.
1	31	93.94	31	93.94
2	2	6.06	33	100.00

Frequency Missing = 1492

B3. Record the volume of the EBST (i.e. PVR): _____ mL → SEE SKIP DIRECTIVE BELOW

Analysis Variable : EBST_PVR								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
1515	0	36.9	54.6	0.0	5.0	20.0	50.0	750.0

EBST_PVR	Frequency	Percent	Cum Freq	Cum Percent
.	10	100.00	10	100.00

Skip to C3 if EBST is positive at a volume ≤300mL and PVR demonstrates adequate voiding, i.e. PVR <100mL and < 1/3 total bladder volume. NOTE: A retrograde fill IS required...

- to perform a FBST if the EBST is negative or positive at >300mL; OR
- to repeat measures of voided volume and PVR if preliminary PVR is >100mL or >1/3 total bladder volume.

B4. Was the bladder filled to 300mL or to an MCC <300mL? 300mL1 → SKIP TO B5 IF FBST IS REQUIRED, ELSE SKIP TO C1

MCC <300mL2

BLAD_FILL	Frequency	Percent	Cum Freq	Cum Percent
.	90	.	.	.
1	1246	86.83	1246	86.83
2	189	13.17	1435	100.00

Frequency Missing = 90

B3a. Is question B4 Completed? (B4_comp)

B4_COMP	Frequency	Percent	Cum Freq	Cum Percent
1	1497	98.16	1497	98.16
2	28	1.84	1525	100.00

B4a. Record MCC: _____ mL →SKIP TO C1 IF FBST IS NOT REQUIRED

Analysis Variable : MCC									
N	Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum	
250	0	251.6	45.4	55.0	225.0	250.0	290.0	400.0	

MCC	Frequency	Percent	Cum Freq	Cum Percent
.	1275	100.00	1275	100.00

B5. Outcome of **full bladder stress test (FBST)**:

- Positive without reduction..... 1
- Positive with reduction..... 2
- Negative **3 → SKIP TO SECTION C**

FULL_BLAD_ST	Frequency	Percent	Cum Freq	Cum Percent
.	30	.	.	.
1	193	12.91	193	12.91
3	1302	87.09	1495	100.00

Frequency Missing = 30

B5a. Was the full bladder stress test positive ...

	YES	NO	NOT TESTED
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i. ...with Valsalva in dorsal lithotomy position*? 1 2 3

DOR_VAL	Frequency	Percent	Cum Freq	Cum Percent
.	1332	.	.	.
1	52	26.94	52	26.94
2	139	72.02	191	98.96
3	2	1.04	193	100.00

Frequency Missing = 1332

ii. ...with cough in dorsal lithotomy position*? 1 2 3

DOR_COUGH	Frequency	Percent	Cum Freq	Cum Percent
.	1332	.	.	.
1	101	52.33	101	52.33
2	74	38.34	175	90.67
3	18	9.33	193	100.00

Frequency Missing = 1332

iii. ...with Valsalva standing?..... 1 2 3

STAND_VAL	Frequency	Percent	Cum Freq	Cum Percent
.	1332	.	.	.
1	51	26.42	51	26.42
2	66	34.20	117	60.62
3	76	39.38	193	100.00

Frequency Missing = 1332

iv. ...with cough standing?..... 1 2 3

STAND_COUGH	Frequency	Percent	Cum Freq	Cum Percent
.	1332	.	.	.
1	83	43.01	83	43.01
2	23	11.92	106	54.92
3	87	45.08	193	100.00

Frequency Missing = 1332

B4b. Are questions B5 and B5a completed? (B5_comp)

B5_COMP	Frequency	Percent	Cum Freq	Cum Percent
.	28	.	.	.
1	1496	99.93	1496	99.93
2	1	0.07	1497	100.00

Frequency Missing = 28

* These maneuvers are not required during the FBST *with reduction*.

Affix ID Label Here

SECTION C: REPEAT MEASURES OF VOIDED VOLUME AND PVR

If repeat measures of voided volume and PVR are not required, do not record values in C1-C2a.

C1. Voided volume: _____ mL

Analysis Variable : VOID_VOL

N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
477	0	305.4	59.7	50.0	300.0	300.0	325.0	600.0

VOID_VOL	Frequency	Percent	Cum Freq	Cum Percent
.	1048	100.00	1048	100.00

C2. PVR _____ mL → NOTE: PVR WILL BE A NEGATIVE VALUE IF THE VOIDED VOLUME IS > VOLUME OF THE FILL

Analysis Variable : PVR								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
331	0	26.4	50.2	0.0	0.0	5.0	30.0	350.0

PVR	Frequency	Percent	Cum Freq	Cum Percent
.	1194	100.00	1194	100.00

C2a. Was this PVR...

Calculated?1

Measured per catheterization?2

PVR should be measured (code 2) if

- The void is > 10 minutes after the fill or
- The VV is 50cc > the fill volume

PVR_METHOD	Frequency	Percent	Cum Freq	Cum Percent
.	1047	.	.	.
1	389	81.38	389	81.38
2	89	18.62	478	100.00

Frequency Missing = 1047

C0: Are questions C1, C2 and C2a completed?

C1_COMP	Frequency	Percent	Cum Freq	Cum Percent
.	78	.	.	.
1	480	33.17	480	33.17
2	967	66.83	1447	100.00

Frequency Missing = 78

C3. Was a prophylactic antibiotic given? Yes 1

No 2

ANTIBIOTIC	Frequency	Percent	Cum Freq	Cum Percent
1	309	20.26	309	20.26
2	1216	79.74	1525	100.00

SECTION D: OUTCOMES

D1. Did the patient demonstrate SUI at a bladder volume ≤300mL during the TOMUS Stress Test?

Yes..... 1 → COMPLETE FAILURE PROTOCOL

No 2

SUI	Frequency	Percent	Cum Freq	Cum Percent
.	3	.	.	.
1	219	14.39	219	14.39
2	1303	85.61	1522	100.00

Frequency Missing = 3

D2. Date Testing Completed: ____ / ____ / ____
Month Day Year

D3. Examiner's ID: ____

D4. Date Abstract Completed: ____ / ____ / ____
Month Day Year

D5. Abstractor's ID: ____

TOMMUS