



## Simple Bladder Testing Procedures Manual

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### BASELINE MEASURES

**OVERVIEW:** Patients will be tested at baseline to determine eligibility on three criteria: 1) evidence of stress urinary incontinence at a bladder volume  $\leq 300\text{mL}$ ; 2) adequate bladder capacity during stress test, i.e.  $\geq 200\text{mL}$  and, 2) adequate emptying capability, i.e. PVR  $\leq 100\text{mL}$  with POP  $\leq$  Stage 1; or PVR  $\leq 500\text{mL}$  if POP is Stage II-IV.

Testing steps should be completed sequentially in the order prescribed below. Testing is complete when all eligibility criteria have been met or the patient is determined to be ineligible. Because the ability to empty may be compromised at low bladder volumes, PVR can be measured again after the FBST if the initial PVR does not meet eligibility criterion.

If a subject has an anterior POP Stage III or IV, and does not leak during the Empty Bladder Stress Test (EBST), the prolapse is reduced and the EBST repeated. If the Full Bladder Stress Test (FBST) is negative without reduction, subjects with anterior POP Stage III or IV are reduced and re-tested standing prior to the void. See procedures below.

### TESTING PROCEDURES:

1. Instruct the subject to void into a toilet hat prior to stress testing and measure the voided volume.
2. **Empty Bladder Stress Test: (EBST)** is performed with the subject in the dorsal lithotomy position. Perform Valsalva maneuver first, followed by cough. NOTE: Repeat both maneuvers with prolapse reduction using a gauze vaginal pack or sponge stick if the EBST is negative and the subject has a Stage III or IV anterior prolapse. Remove reduction and proceed.
3. Place catheter into urethra to empty bladder and determine the volume of the EBST, i.e. PVR.

3a. *Testing is complete if the patient is eligible by all three criteria:*

- *bladder capacity (voided volume + PVR) is  $\geq 200\text{ mL}$ , **and***
- *EBST is positive **and***
- *PVR is  $\leq 100\text{mL}$  with POP  $\leq$  Stage 1 or  $\leq 500\text{mL}$  if POP is Stage II-IV.*

If any of these three eligibility criteria is not met, proceed with the retrograde fill.

4. **Retrograde fill:** Obtain UA to rule out UTI prior to the retrograde fill. Perform retrograde fill to 300mL or bladder capacity, whichever is less.

4a. *Testing is complete now if the patient is ineligible by bladder capacity, i.e.  $< 200\text{mL}$ . NOTE: Bladder capacity is determined from either the EBST (voided volume + PVR) or the volume of the fill for the FBST.*

**Or**

*The patient is eligible on all three criteria:*

- *bladder capacity  $\geq 200\text{ mL}$  (VV + PVR or volume of the fill) **and***
- *EBST positive **and***
- *PVR  $\leq 100\text{mL}$  with POP  $\leq$  Stage 1 or  $\leq 500\text{mL}$  if POP is Stage II-IV.*

NOTE: The Full Bladder Stress Test is not required if the Empty Bladder Stress Test is positive and the patient meets both the bladder capacity and PVR eligibility criteria.

5. **Full Bladder Stress Test (FBST):** Perform Valsalva followed by cough maneuver, first in supine then in standing position. Stop the FBST at any point the test is positive. NOTE: If the FBST is negative in subjects with Stage III or IV anterior prolapse, reduce the prolapse with a gauze vaginal pack or sponge stick and repeat the FBST in the standing position. It is not required to perform provocative maneuvers in the dorsal lithotomy position with reduction.

5a. *Testing is complete now if the patient is ineligible by bladder capacity (i.e. <200ml), or the stress test is negative. NOTE: Bladder capacity is determined from either the EBST (voided volume + PVR) or the volume of the fill for the FBST.*

**Or**

*The patient is eligible on all three criteria:*

- *bladder capacity  $\geq 200$  mL (VV + PVR or volume of the fill) **and***
- *FBST positive **and***
- *PVR  $\leq 100$  mL with POP  $\leq$  Stage I or  $\leq 500$  mL if POP is Stage II-IV.*

If the patient's EBST PVR did not meet eligibility criterion, another PVR should be measured after the FBST to re-test the patient's emptying capability (PVR). Otherwise, measurements of voided volume and PVR post FBST are **not** required and should not be recorded on the TOMUS data form.

6. If a repeat PVR is required, instruct the subject to void into a toilet hat within 10 minutes of the retrograde fill and measure the voided volume.

6b. **PVR:** Catheterize the subject to measure the PVR if the subject voids >10 minute after the fill or the voided volume is more than 50cc greater than the fill volume. Otherwise, calculate the PVR; i.e.  $PVR_{calc} = \text{Volume of the fill} - \text{the voided volume}$

Note: The voided volume may be greater than the volume of the retrograde fill due to physiological filling during testing. For these subjects, record a negative value for the PVR; e.g. the subject is filled to 300mL, 8 minutes later she voids 310mL; record -10 as the PVR. But if the calculated PVR is less than -50, catheterize the subject to measure PVR.

7. Prophylactic antibiotic may be prescribed per surgeon's discretion, if the subject has not received antibiotics within 24 hours.

8. **TOMUS Documentation:** The following procedural and outcome data must be recorded in a source document and abstracted onto the TOMUS baseline Data Form (F313)

**For all subjects:**

- Voided volume prior to the EBST (mL).
- Outcome of the EBST (positive without reduction / positive with reduction / negative)
- If EBST is positive,
  - With what maneuvers? (Valsalva / cough)
- Volume of the EBST, i.e. PVR (mL)

**For subjects who require a retrograde fill to determine adequate bladder capacity:**

- Volume of the retrograde fill: 300mL or maximum capacity (if <300mL, specify capacity)

**For subjects who require a retrograde fill to complete the FBST:**

- Volume of the retrograde fill: 300mL or maximum capacity (if <300mL, specify capacity)
- Outcome of the FBST (positive without reduction / positive with reduction / negative)
- If full bladder stress test is positive,
  - In what position? (supine / standing)
  - With what maneuver? (Valsalva / cough)

**For subjects who require a retrograde fill to repeat PVR to evaluate emptying capability,**

- Volume of the retrograde fill: 300mL or maximum capacity (if <300mL, specify capacity)
  - Volume voided (mL)
  - PVR (mL)
  - PVR calculated or measured (calculated / measured)

**For all subjects:**

- Prophylactic antibiotic given (yes/no)
- Eligibility Determination:
  - Eligibility per stress test (eligible / not eligible)  
*The subject is eligible if the stress test is positive at a bladder volume  $\leq 300\text{mL}$*
  - Eligibility per PVR (eligible / not eligible)  
*The subject is eligible if PVR is  $\leq 100\text{mL}$  with POP  $\leq$  Stage I;  
If POP is Stage II-IV, PVR  $> 100\text{mL}$  but  $\leq 500\text{mL}$  is allowed.*
  - Eligibility per bladder capacity (eligible / not eligible)  
*The subject is eligible if bladder capacity is  $\geq 200\text{mL}$  during Stress Test.*

## POST-OPERATIVE VOIDING TRIAL PRIOR TO DISCHARGE

**OVERVIEW:** For most subjects, the post operative voiding trial will be performed on the day of surgery, prior to discharge, although subject-specific circumstances may cause a delay in the performance of this voiding trial, e.g. concurrent surgical procedures, intra-operative bladder injuries, etc. The post-op voiding trial is performed after a retrograde fill to 300mL or bladder capacity which ever is less.

### RETROGRADE FILL VOIDING TRIAL PROCEDURES:

1. Most subjects will have a urethral catheter in place.
2. **Retrograde fill:** Be sure the subject's bladder is empty prior to the retrograde fill. Perform a retrograde fill to 300mL or bladder capacity, whichever is less. Remove the catheter.
3. **Voiding trial:** Instruct the subject to void into a toilet hat within 10 minutes of the retrograde fill.
  - 3a. **Voided volume:** Measure the voided volume.
  - 3b. **PVR:** Catheterize the subject to measure the PVR if the subject voids >10 minute after the fill or when the voided volume is more than 50cc greater than the fill volume. Otherwise, calculate the PVR, i.e.  $PVR_{calc} = \text{Volume of the fill minus the voided volume}$ 

Note: The voided volume may be greater than the fill volume due to physiological filling during testing. For these subjects, record the negative value for the PVR. But if the calculated PVR is less than -50, catheterize the subject to measure PVR.
4. Determine the **outcome of the voiding trial** (pass/fail).
 
$$Pass = PVR \leq 100cc \text{ and } \leq 1/3 \text{ of total bladder volume}$$
  - 4a. Multiple retrograde fills are not required. If a patient fails her initial retrograde fill trial, subsequent pre-discharge trials may be performed as passive fill trial following TOMUS procedures described in this document. However, PVR must be measured by catheter (i.e. not by bladder scan).
5. Document the **bladder management plan:** If subject does not "pass" the voiding trial, the TOMUS surgeon or TOMUS designee may choose to continue bladder management using a urethral catheter, teach CISC, or approve unassisted voiding at discharge. An interim voiding trial is required on post-op Day 2-4 for subjects who do not pass the voiding trial prior to discharge.
6. **TOMUS Documentation:** The following procedural and outcome data must be recorded in a source document and abstracted onto the TOMUS Discharge Measures Data Form (F311):
  - The date of the last retrograde fill voiding trial performed prior to discharge. (NOTE: the time (in days) of the post-op retrograde fill voiding trial relative to date of surgery (DOS, POD<sub>1,2,3</sub>) will be computed.
  - As needed, reasons why a voiding trial was not performed prior to discharge or why it was performed later than the date of surgery:
    - concurrent surgery
    - bladder perforation
    - vaginal pack
    - regional anesthesia
    - over sedation
    - excessive discomfort
    - staffing constraints
    - other (specify)
  - Volume of the retrograde fill. 300mL or bladder capacity (If <300mL, specify volume);
  - Volume voided (mL);
  - PVR (mL);
  - PVR calculated or measured (calculated / measured);

- Total bladder volume (voided volume + PVR will be computed by the DMS);
- Outcome of the trial: (pass / fail): *i.e. Pass = PVR  $\leq 100\text{cc}$  and  $\leq 1/3$  of total bladder volume)*
- Bladder management plan at discharge (urethral catheter / CISC / self voiding).

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## INTERIM VOIDING TRIAL(S)

**OVERVIEW:** One or more interim voiding trials should be performed between surgery and the 2-week post-op visit for subjects who do not ‘pass’ the voiding trial prior to discharge (i.e. PVR >100mL or >1/3 of total bladder volume) **and** for those subjects who require catheterization (Foley or CISC) subsequent to discharge.

The **first** interim voiding trial should be performed two to four days post-op. Additional interim trials may be performed q 2-4 days if clinically warranted as determined by the surgeon or his/her TOMUS designee.

Interim trials may be performed at the surgeon’s office or clinic, at the CTC research site, at the referring physician’s office or clinic, or by a visiting nurse at the subject’s home. Regardless of where the trial is performed, TOMUS voiding trial procedures should be followed.

Acceptable trial procedures include:

- Retrograde fill voiding trial (preferred)
- Passive fill voiding trial (*only* if retrograde fill is not feasible)
- Voiding trial for subjects performing CISC

### **Retrograde fill voiding trial:**

1. If the subject has a urethral catheter, be sure to drain the bladder completely prior to starting the retrograde fill. If the subject does not have a catheter in her bladder, insert one using sterile technique.
2. **Retrograde fill:** Attach a Toomey syringe to the intravesical catheter and retrograde fill the bladder to 300mL or MCC, whichever is less. Remove the catheter.
3. **Voiding trial:** Instruct the subject to void into a toilet hat within 10 minutes of the retrograde fill. Give the subject as much privacy as possible.
  - 3a. **Voided volume:** Measure the voided volume.
  - 3b. **PVR:** Catheterize the subject to measure the PVR if the subject voids >10 minute after the fill or when the voided volume is more than 50cc greater than the fill volume. Otherwise, calculate the PVR, i.e.  $PVR_{calc} = \text{Volume of the fill} - \text{the voided volume}$   
  
Note: The voided volume may be greater than the fill volume due to physiological filling during testing. For these subjects, record the negative value for the PVR. But if the calculated PVR is less than -50, catheterize the subject to measure PVR.
4. Review the finding of the voiding trial with the patient’s surgeon to determine the bladder management plan.
5. Document the **bladder management plan:** If subject does not “pass” the voiding trial, the TOMUS surgeon or TOMUS designee may choose to continue bladder management using a urethral catheter, starting or continuing CISC, approve unassisted voiding with or without additional interim voiding trials prior to the 2-week post-op visit, etc.
6. **Prophylactic antibiotic** may be prescribed per surgeon’s discretion, if the subject has not received antibiotics within 24 hours.

### **Passive Fill Voiding Trial:**

A passive fill voiding trial may be completed *only*, if a retrograde fill is not feasible, for example, interim voiding trial performed by a visiting nurse **who is not authorized** to complete a retrograde fill in a subject's home. NOTE: A passive fill voiding trial should be conducted when the bladder is near full. Subjects should be strongly encouraged to drink a sufficient amount of fluid prior to the void.

1. If the subject has a urethral catheter, plan to have it removed 3 to 6 hours prior to this voiding trial.
2. Instruct subject to void in a toilet hat when she has a natural urge to void. Measure and record the voided volume. Empty the toilet hat.
3. Catheterize the subject and measure PVR within 10 minutes of voiding (if possible) and within six hours of removing catheter.  
If voided volume is not known, a PVR  $\leq 100$ cc will be accepted as a pass if the subject reports she feels empty. [ASK HER: "DO YOU FEEL EMPTY"? "DO YOU FEEL LIKE YOU EMPTIED YOUR BLADDER?"].
4. Review the finding of the voiding trial with the patient's surgeon to determine the bladder management plan.
5. Document the **bladder management plan**: If subject does not "pass" the voiding trial, the TOMUS surgeon or TOMUS designee may choose to continue bladder management using a urethral catheter, starting or continuing CISC, approving unassisted voiding with or without additional interim voiding trials prior to the 2-week post-op visit, etc.
6. **Prophylactic antibiotic** may be prescribed per surgeon's discretion, if the subject has not received antibiotics within 24 hours.

### **Interim Voiding Trial for Subjects Performing CISC:**

If the subject is performing CISC, follow these procedures. NOTE: the voiding trial for subjects performing CISC should be conducted when the bladder is near full. Subjects should be strongly encouraged to drink a sufficient amount of fluid prior to the void.

1. Instruct subject to void in a toilet hat when she has a natural urge to void; measure and record the voided volume; and, empty the toilet hat.
2. The subject can be catheterized or she may perform self catheterization per CTC protocol immediately after the void. The PVR should be measured as a separate volume using a graduated container.
3. Review the finding of the voiding trial with the patient's surgeon to determine the bladder management plan.
4. Document the **bladder management plan**: If subject does not "pass" the voiding trial, the TOMUS surgeon or TOMUS designee may choose to continue bladder management per CISC, use a urethral catheter, prescribe unassisted voiding with or without additional interim voiding trials prior to the 2-week post-op visit, etc.
5. **Prophylactic antibiotic** may be prescribed per surgeon's discretion, if the subject has not received antibiotics within 24 hours.

**Documentation:** Procedures followed and testing outcomes should be recorded in a source document and abstracted onto the TOMUS Data Form (F320) at the 2-week post op visit.

- The date of the trial
- Type of trial (retrograde / passive fill / CISC)
- For retrograde fills, volume of the fill (mL)
- Voided volume (mL)
- PVR (mL)
- PVR calculated or measured

- Prophylactic antibiotics given (yes/ no)
- Total bladder volume (voided volume + PVR will be computed by the DMS);
- Outcome of the voiding trial (pass / fail will be computed by the DMS)
- Bladder management after the trial (unassisted / urethral catheter / CISC / other)
- Record of person who completed the voiding trial (TOMUS Staff ID or text description of someone else)

CLARIFICATION ADDED 6/13/06: For a patient performing CISC who does not have a clinically supervised interim voiding trial, or for a patient who continues CISC subsequent to a supervised interim trial, record the date/data from her last CISC procedure. Do not record data from unsupervised CISC procedures if the patient is still performing CISC at the time of the 2 week study visit.

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## MEASUREMENT OF PVR AT THE 2-WEEK AND 6-WEEK POST-OP VISITS

**OVERVIEW:** The voiding trial performed at the 2-week and 6-week post op visit may be conducted as a passive fill voiding trial using a bladder scanner to estimate PVR or a catheter to measure PVR, or a retrograde fill trial may be performed. But the patient must be catheterized to measure PVR if the PVR by bladder scan is >75 cc, and a retrograde fill is required if the PVR measured by catheter from a passive fill is >100cc.

Testing steps should be completed sequentially in the order prescribed below.

### **Passive fill voiding trial with bladder scanner:**

1. Instruct subject to void in a toilet hat. Give the subject as much privacy as possible. Measure and record the voided volume.
2. Scan the bladder to estimate the PVR.
3. Record the PVR and determine the **outcome of the voiding trial.**
  - Testing is complete if  $PVR_{scan}$  is < 75 cc. Skip to Step #10 below.
  - If  $PVR_{scan} \geq 75cc$ , place catheter to empty bladder
    - Testing is complete if  $PVR_{cath} \leq 100cc$  OR if  $PVR_{cath} > 100cc$  with a total bladder volume  $\geq 300cc$ . Skip to Step #10 below.
    - Perform a retrograde fill and repeat the voiding trial if  $PVR_{cath} > 100cc$  with total bladder volume <300cc.

### **Retrograde fill voiding trial:**

4. **Retrograde fill:** Perform a retrograde fill to 300mL or maximum capacity, whichever is less.
5. Instruct the subject to void into a toilet hat within 10 minutes of the retrograde fill. Give the patient as much privacy as possible.
6. Measure the voided volume.
7. Determine the PVR:
  - PVR should be calculated if the patient voids within 10 minutes of the fill
 
$$PVR_{calc} = \text{Volume of the fill} - \text{the voided volume}$$
  - Catheterize patient to measure the actual PVR if
    - the void is > 10 minutes after the fill or
    - if the voided volume is more than 50cc greater than the fill volume.

Note: The voided volume may be greater than the volume of the fill due to physiological filling during testing. For these subjects, record the PVR as a negative value on the F330. But if the calculated PVR is less than -50, catheterize the subject to measure PVR.
8. **Prophylactic antibiotic** may be prescribed per surgeon's discretion, if the subject has not received antibiotics within 24 hours.
9. Discuss the finding of the voiding trial with the patient's surgeon and determine the bladder management plan.

10. Document the bladder management plan, e.g. self-voiding only, use of a urethral catheter, starting or continuing CISC sometimes or always, or some other bladder management plan, e.g. plans for surgical treatment, i.e. sling release, sling stretching, sling excision, or urethrolysis.
11. If the patient requires assistance to void, record the voiding dysfunction on the Follow-up Physicians Assessment Forms (F322).

**Documentation:** The following procedural and outcome data must be recorded in a source document and abstracted onto the TOMUS Data Form, F330:

- Data from passive fill voiding trial:
  - Volume voided (ml)
  - PVR by bladder scan (mL)
  - Passive fill PVR by catheter (mL)
- Data from standard volume retrograde fill voiding trial:
  - Volume of the fill: 300mL or MCC (If <300mL, specify volume)
  - Volume voided (mL)
  - PVR (mL)
  - PVR calculated or measured (calculated / measured)
- Prophylactic antibiotics given (yes/ no)
- Bladder management after the trial (unassisted / Foley catheter / CISC / other)
- Outcome of the voiding trial (pass / fail will be computed by the DMS)

**STRESS TEST AND PVR MEASURES AT THE 6, 12 AND 24 MONTHS POST-OP VISITS**

**OVERVIEW:** The provocative stress test and measure of PVR are repeated at the 6, 12 and 24 month post-op visits. Provocative stress testing is performed as a surgical treatment outcome measure. Treatment success is defined as a negative stress test at a bladder volume  $\geq 300\text{mL}$  or capacity, whichever is less. Treatment failure is defined as positive Stress Test at a bladder volume  $\leq 300\text{mL}$ . The PVR is performed as a measure of bladder emptying capability.

Testing steps should be completed sequentially in the order prescribed below. Patients with Stage III or IV anterior pelvic organ prolapse who do not leak when stress tested should have their prolapse reduced and provocative maneuvers should be repeated in order to determine the presence of stress urinary incontinence by provocative Stress Test with reduction of the obstructing prolapse.

**TESTING PROCEDURES:**

1. Instruct the subject to void in a toilet hat prior to stress testing and measure the voided volume.
2. Perform an **Empty Bladder Stress Test (EBST)** with the subject in the dorsal lithotomy position. Perform Valsalva maneuver first, followed by cough. [NOTE: Repeat both maneuvers with prolapse reduction using a gauze vaginal pack or sponge stick if the EBST is negative and the subject has a Stage III or IV anterior prolapse. Remove reduction and proceed.]
3. Place catheter to empty bladder and determine the volume of the EBST, i.e. PVR.

*3a. Testing is complete if the stress test is positive and the PVR is  $< 100\text{mL}$  and  $< 1/3$  of the total bladder volume.*

*Perform a retrograde fill and complete the FBST and/or fill and flow voiding trial as warranted:*

*A FBST is required if the EBST is negative or if the EBST is positive at a volume  $> 300\text{mL}$ .*

*A standard volume voiding trial is required if the PVR is  $> 100\text{mL}$  or  $> 1/3$  the total bladder volume.*

4. **Retrograde fill:** Obtain UA to rule out UTI prior to the retrograde fill. Perform retrograde fill to 300mL or bladder capacity, whichever is less.
5. **Full Bladder Stress Test (FBST):** Perform Valsalva followed by cough maneuver, first in supine then in standing position. Stop the FBST at any point the test is positive. [NOTE: If the FBST is negative in subjects with Stage III or IV anterior prolapse, reduce the prolapse with a gauze vaginal pack or sponge stick and repeat the FBST in the standing position. It is not required to perform provocative maneuvers in the dorsal lithotomy position with reduction.]

*5a. If indicated, measure the voided volume and PVR to re-test the patient's emptying capability (PVR). Otherwise, measurements of voided volume and PVR post FBST are **not** required and should not be recorded on the TOMUS data form.*

6. If a repeat voiding trial is required, instruct the subject to void into a toilet hat within 10 minutes of the retrograde fill and measure the voided volume.

- 6a. **PVR:** Catheterize the subject to measure the PVR if the subject voids >10 minute after the fill or the voided volume is more than 50cc greater than the fill volume. Otherwise, calculate the PVR; i.e.  $PVR_{calc} = \text{Volume of the fill} - \text{the voided volume}$ .

Note: The voided volume may be greater than the volume of the retrograde fill due to physiological filling during the FBST. Negative values up to -50mL may be recorded on the data form. But if the calculated PVR is less than -50, catheterize the subject to measure PVR.

7. Prophylactic antibiotic may be prescribed per surgeon's discretion, if the subject has not received antibiotics within 24 hours.
8. **TOMUS Documentation:** The following procedural and outcome data must be recorded in a source document and abstracted onto the TOMUS Data Form (F353)

**For all subjects:**

- Voided volume prior to the EBST (mL).
- Outcome of the EBST (positive without reduction / positive with reduction / negative)
- If EBST is positive,
  - With what maneuvers? (Valsalva / cough)
- Volume of the EBST, i.e. PVR (mL)

**For subjects who require a retrograde fill FBST:**

- Volume of the retrograde fill (mL)
- Outcome of the FBST (positive without reduction / positive with reduction / negative)
- If full bladder stress test is positive,
  - In what position? (supine / standing)
  - With what maneuver? (Valsalva / cough)

**For subjects who require a retrograde fill to repeat PVR to evaluate emptying capability,**

- Volume of the retrograde fill (mL)
- Volume voided (mL)
- PVR (mL)
- PVR calculated or measured (calculated / measured)

**For all subjects:**

- Prophylactic antibiotic given (yes/no)
- Demonstrated Stress Urinary Incontinence at  $\leq 300\text{mL}$  (yes/ no)