



**Question by Question Specifications Guide**  
**Form 94: Failure**  
**Version 08/05/04 (B)\_revised 10/11/05**

## **I. Purpose**

The purpose of the Failure Data Form is to document the reason(s) why a patient is determined to be a treatment failure following her UITN surgery for stress urinary incontinence (SUI). If a patient is a treatment failure and is going to undergo surgical retreatment, then the entire 24-month battery should be conducted prior to surgery, including UDS. If a patient is a treatment failure and is going to either forego retreatment OR be retreated with medication and/or behavioral therapy, the 24-month battery, excluding UDS and FM60, should be conducted at the time of failure and before any retreatment is initiated. Treatment failures are still in the trial and should continue with the visit schedule as outlined in the protocol. If the out-of-sequence 24-month assessment is performed within the specified window for the next assessment, then that next assessment can be omitted. The Failure Protocol and “Treatment Failure” definitions are attached as an Appendix to this QxQ.

## **II. Administration**

### **A. When to Use This Data Form**

This Data Form should be completed to document treatment failure upon conclusion of the visit associated with the Failure protocol. If treatment for SUI is reported, “Data Form 93: Reintervention or Treatment” must also be completed. The treatment failure battery does not have to be conducted again. For example, if a patient fails the Stress Test at 6-months but does not opt for retreatment because she is still satisfied with her surgical result, the 24-month battery, excluding UDS and FM60, should be conducted, and a FM94 should be completed to document that the patient failed the Stress Test. If the patient comes in at 12 months with self-reported leakage by voiding diary, the failure battery does not have to be repeated as these measures were conducted at 6 months. But, a FM94 should be completed to indicate that the patient now has self-reported leakage by voiding diary. In essence, the BCC needs the first date of failure for each individual failure component. If more than one “first” failure occurs during the same visit, these can be documented on a single FM94.

### **B. Source**

The source of this information will be UITN surgeons, Study Coordinators and/or the patient. Source documents and/or medical records will be required to support these data.

## **III. Section by Section Review**

### **Section A: General Study Information**

- A1. **Study ID Number:** Affix the patient ID label in the space provided in the A1 field. As with all other Data Forms, do not handwrite ID numbers.
- A2. **Visit Number:** The visit number is pre-coded for Form 94 which will always be Visit **FAIL**.
- A3. **Date Form Completed:** Enter the date the form was completed in the format of mm/dd/yyyy.
- A4. **Initials of Person Completing this Form:** Enter the initials of the person completing this form. Enter first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If you do not have a middle initial, strike a dash in the second space. If your last name is hyphenated or if you have two last names, enter initial of the first last name in the third space.
- A5. **Is this Treatment Failure associated with a UITN study visit?** Circle yes (code 1) or no (code 2). If “no,” skip to B1.
- A6. **With which visit is this failure associated?** Circle the appropriate visit code.

**Section B: Treatment Failure**

- B1. **Positive Stress Test:** Record whether or not the patient demonstrated SUI during the Stress Test; circle yes (code 1) or no (code 2). If “no,” skip to B2.
- B1a. **Date of Failure:** Record the date that the Stress Test was completed as the date of failure in the format of mm/dd/yyyy.
- B2. **Self-reported stress-type UI symptoms (MESA):** Record whether or not the patient reported stress type UI symptoms (response of “sometimes” or “often” on the MESA questionnaire) on a follow-up MESA interview; circle yes (code 1) or no (code 2). If “no,” skip to B3.
- B2a. **Date of Failure:** Record the date that the MESA was completed as the date of failure in the format of mm/dd/yyyy.
- B3. **Positive Pad Test:** Record whether or not the patient had a Positive Pad Test ( $\geq 15$ ml leakage over 24 hours); circle yes (code 1) or no (code 2). If “no,” skip to B4.
- B3a. **Date of Failure:** Record the date that the Pad Test was completed as the date of failure in the format of mm/dd/yyyy.
- B4. **Self-reported leakage by the 3-day Voiding Diary:** Record whether or not the patient reported leakage by the 3-day Voiding Diary; circle yes (code 1) or no (code 2). If “no,” skip to B5.
- B4a. **Date of Failure:** Record the first date that the patient leaked as the date of failure in the format of mm/dd/yyyy.
- B5. **Surgical retreatment for SUI:** Record whether or not the patient received surgical retreatment for SUI; circle yes (code 1) or no (code 2). If “no,” skip to B6.
- B5a. **Date of Failure:** Record the date of the surgery as the date of failure in the format of mm/dd/yyyy.
- B6. **Pharmacologic treatment for SUI:** Record whether or not the patient received pharmacologic treatment for SUI; circle yes (code 1) or no (code 2). If “no,” skip to B7.
- B6a. **Date of Failure:** Record the date that the patient first started taking the medication as the date of failure in the format of mm/dd/yyyy.
- B7. **Behavioral treatment for SUI:** Record whether or not the patient received behavioral treatment for SUI; circle yes (code 1) or no (code 2). If “no,” skip to B8.
- B7a. **Date of Failure:** Record the date that the patient first started receiving behavioral treatment as the date of failure in the format of mm/dd/yyyy.
- B8. **Device treatment for SUI:** Record whether or not the patient received treatment with a device for SUI; circle yes (code 1) or no (code 2). If “no,” skip to B9.
- B8a. **Date of Failure:** Record the date of treatment with a device as the date of failure in the format of mm/dd/yyyy.
- B9. **Other treatment for SUI:** Record whether or not the patient received other treatment for SUI; circle yes (code 1) or no (code 2). If “no,” skip to “Principal Investigator’s Signature” and “Date.”
- B9a. **Specify:** Record a detailed description of the “other” treatment for SUI in the space provided.
- B9b. **Date of Failure:** Record the date that other treatment was received as the date of failure in the format of mm/dd/yyyy.

**IN ORDER FOR THIS DATA FORM TO BE COMPLETE,  
THE PRINCIPAL INVESTIGATOR MUST SIGN AND DATE THE FORM  
IN THE SPACE PROVIDED.**

## FAILURE PROTOCOL

### From page 10 of the Study Protocol

#### Overall treatment failure is defined as:

- any surgical, pharmacological or behavioral retreatment for SUI at any point after the initial surgery for urine leakage; or
- any one of the following  $\geq 6$  months after surgery:
  1. a positive stress test, or
  2. self-reported stress-type UI symptoms (response of “sometimes” or “often” on the MESA questionnaire); or
  3. a positive pad test ( $\geq 15$  ml leakage over 24 hours), or
  4. self-reported leakage by 3-day voiding diary.

#### Treatment failure specific to SUI is defined as:

- any surgical, pharmacological or behavioral retreatment for SUI at any point after the initial surgery for urine leakage; or
- any one of the following  $\geq 6$  months after surgery:
  1. a positive stress test, or
  2. self-reported stress-type UI symptoms (response of “sometimes” or “often” on the MESA questionnaire)

If a patient is a treatment failure and is going to undergo surgical retreatment, then the entire 24-month battery should be conducted prior to surgery, including UDS. If a patient is a treatment failure and is going to either forego retreatment OR be retreated with medication and/or behavioral therapy, the 24-month battery, excluding UDS and FM60, should be conducted at the time of failure and before any retreatment is initiated. Treatment failures are still in the trial and should continue with the visit schedule as outlined in the protocol.

### Schedule of Measures/Data Forms for Treatment Failure

|   |
|---|
| <b>FM03: Med Audit</b>  |
| <b>FM51: F/U Patient Interview</b>                              |
| <b>FM52: F/U Physician Assessment</b>                           |
| <b>FM53: F/U Stress Test</b>                                    |
| <b>FM54: F/U POP-Q Exam</b>                                     |
| <b>FM55: F/U UDS<sup>‡</sup></b>                                |
| <b>FM56: F/U Pad Test &amp; Voiding Diary Summary</b>           |
| <b>FM57: F/U Patient Survey<sup>†</sup></b>                     |
| <b>FM58: 12 &amp; 24 Month F/U Patient Survey Part II</b>       |
| <b>FM59: F/U Q-Tip Test</b>                                     |
| <b>FM60: 24 Month Physical Systems Update<sup>‡</sup></b>       |
| <b>FM90: Unexpected Event or Protocol Deviation<sup>*</sup></b> |
| <b>FM91: Adverse Event<sup>*</sup></b>                          |
| <b>FM92: Death<sup>*</sup></b>                                  |
| <b>FM93: Reintervention or Retreatment<sup>*</sup></b>          |
| <b>FM94: Failure</b>  |

<sup>\*</sup> Optional/As Needed

<sup>†</sup> If Treatment Failure occurs at or before the 6 Month Visit, patient should complete FM47 in lieu of FM57.

<sup>‡</sup> FM55/UDS and FM60 should only be completed if the patient is having surgical retreatment for SUI.