

Section A: General Study Information for Office Use Only:

A1. STUDY ID#:

LABEL

A2. VISIT #

F/U 6 MONTHS	FU06	F/U 12 MONTHS	FU12
F/U 18 MONTHS	FU18	F/U 24 MONTHS	FU24
F/U 30 MONTHS	FU30	F/U 36 MONTHS	FU36
F/U 42 MONTHS	FU42	F/U 48 MONTHS	FU48
F/U 54 MONTHS	FU54	F/U 60 MONTHS	FU60
F/U 66 MONTHS	FU66	F/U 72 MONTHS	FU72
F/U 78 MONTHS	FU78	F/U 84 MONTHS	FU84
FAILURE	FAIL		

A3. Date Form Completed: ____/____/____
 Month Day Year

A4. Initials of Person Completing This Form: ____
 (Certified Surgeon)

SECTION B: PATIENT COMPLICATIONS OR SYMPTOMS

B1. Upon review of Data Form 51, does the patient report any pain that she feels is related to the index surgery for urinary incontinence?

YES..... 1

NO 2 → **SKIP TO B2**

B1a. Do you judge this pain to be related to the index surgery for urinary incontinence?

YES..... 1

NO..... 2 → **SKIP TO B2**

B1b. Were there any treatments given for this complication?

YES 1

NO 2 → **SKIP TO B2**

B1c. Describe this/these treatments: _____

B2. Based upon the patient’s medical history and a review of Data Form 51 is there new or continuing evidence of...

	YES	NO
a. ... urinary retention (defined as catheter use <u>or</u> use of medication to enhance voiding <u>or</u> PVR >150cc).....	1	2
b. ... vaginal prolapse?.....	1	2
c. ... de novo urge incontinence?.....	1	2
d. ... persistent urge incontinence.....	1	2
e. ... stress urinary incontinence?	1	2

B3. Did you code “YES” to any of B2a-e?

- YES..... 1
- NO 2 **➔ SKIP TO B5**

B4. Is there evidence of, or does the patient report, any **new or continuing** treatment for any of the problems in B2a-e?

- YES..... 1 **➔ COMPLETE DATA FORM 93: REINTERVENTION OR TREATMENT**
- NO 2

B5. Is this Form being completed as part of the FU30 visit or beyond?

- YES..... 1
- NO 2 **➔ SKIP TO B7**

B6. Does the patient report or is there new evidence of any of the following reportable E-SISTER adverse events since the last visit?:

	YES	NO
a. Sling erosion	1	2
b. Hernia (incisional)	1	2
c. Erosion of suture material into bladder or vagina (due to Burch/Sling only)	1	2
d. Recurrent cystitis (≥2 occurrences in a 6 month period)	1	2
e. Hydronephrosis	1	2

****REMINDER: “YES” RESPONSES REQUIRE AN ADVERSE EVENT FORM 71****

B7. Is there evidence or does the patient report any **other** symptom or complication related to her incontinence surgery?

YES..... 1 **DOCUMENT ON FM91 OR FM71 AS NECESSARY**

NO 2 **➔END**

B7a. Describe any other symptom or complication related to her incontinence surgery: _____
