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F374: Follow-Up Exam, version 03/09/09 (A)

UITN E-TOMUS

SECTION A: GENERAL STUDY INFORMATION

A1. Study ID#: LABEL

A2. Visit #: F/U 36 Months……ET36 F/U 48 Months…..ET48
F/U 60 Months……ET60 F/U 72 Months…..ET72
F/U 84 Months……ET84

VISIT	Frequency	Percent	Cum Freq	Cum Percent
ET36	343	38.50	343	38.50
ET48	307	34.46	650	72.95
ET60	178	19.98	828	92.93
ET72	63	7.07	891	100.00

A3. Date Exam Completed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)

A4. Examiner's Initials: ____ ____ ____

A5. Date Form Completed: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month Day Year)

A6. Study Staff Initials: ____ ____ ____

SECTION B: ANTHROPOMETRIC MEASURES

B1. Height: ____ ____ inches

B2. Weight: ____ ____ ____ lbs

HEIGHT_NEW	Frequency	Percent	Cum Freq	Cum Percent
	13	.	.	.
60	52	5.92	52	5.92
61	44	5.01	96	10.93
62	103	11.73	199	22.67
63	111	12.64	310	35.31
64	151	17.20	461	52.51
65	138	15.72	599	68.22
66	82	9.34	681	77.56
67	70	7.97	751	85.54
68	46	5.24	797	90.77
<=59	37	4.21	834	94.99
>=69	44	5.01	878	100.00

Frequency Missing = 13

Analysis Variable : WEIGHT								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
881	10	177.0	40.3	101.0	147.0	171.0	201.0	329.0

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SECTION C: URINE DIPSTICK RESULTS

C1. Negative urine dipstick obtained prior to the visit (i.e. results trace or less for leukocytes and — Yes ..... 1 ➔**SKIP TO D1** No..... 2

DIPSTICK_1	Frequency	Percent	Cum Freq	Cum Percent
1: Yes	801	89.90	801	89.90
2: No	90	10.10	891	100.00

C2. Was catheterized specimen obtained and dipstick repeated or urine sent for culture or UA performed? — Yes ..... 1 No..... 2➔**PROTOCOL DEVIATION; COMPLETE F390 & SKIP TO D1**

CATHETER	Frequency	Percent	Cum Freq	Cum Percent
.	801	.	.	.
1: Yes	76	84.44	76	84.44
2: No	14	15.56	90	100.00

Frequency Missing = 801

C3. Was result negative (trace or less) for leukocytes — Yes ..... 1 No..... 2

DIPSTICK_2	Frequency	Percent	Cum Freq	Cum Percent
.	815	.	.	.
1: Yes	37	48.68	37	48.68
2: No	39	51.32	76	100.00

Frequency Missing = 815

REMINDER: COMPLETE FE91 AS NECESSARY (e.g. RECURRENT UTI EVENTS)

SECTION D: PELVIC ORGAN PROLAPSE QUANTIFICATION EXAM

	POINT	[DESCRIPTION]	VALUE	RANGE	NA
D1.	**Aa**	anterior wall 3 cm from external urethral meatus	____ ____ ____ . ____	-03 to +03	

Analysis Variable : POPQ_AA								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
883	8	-2.0	1.0	-3.0	-3.0	-2.0	-1.5	3.0

D2.	**Ba**	most dependent part of anterior wall	____ ____ ____ . ____	-03 to +TVL

Analysis Variable : POPQ_BA								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
883	8	-2.0	1.0	-3.0	-3.0	-2.0	-1.5	3.0

FINAL VERSION

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D3.	**C**	cervix or vaginal cuff.....	____ ____ ____ . ____	± TVL

Analysis Variable : POPQ_C								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
883	8	-7.2	2.2	-12.0	-8.0	-7.5	-6.5	11.0

D4.	**D**	posterior fornix (if no prior total hyst).....	____ ____ ____ . ____	± TVL	888

Analysis Variable : POPQ_D								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
884	7	429.8	448.2	-13.0	-9.0	9.0	888.0	888.0

D5.	**Ap**	posterior wall 3 cm from hymen.....	____ ____ ____ . ____	-03 to +03

Analysis Variable : POPQ_AP								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
884	7	-2.2	0.9	-3.0	-3.0	-2.0	-2.0	2.0

D6.	**Bp**	most dependent part of posterior wall.....	____ ____ ____ . ____	-03 to +TVL

Analysis Variable : POPQ_BP								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
884	7	-2.2	0.9	-3.0	-3.0	-2.0	-2.0	3.0

D7.	**GH**	genital hiatus (mid urethral meatus to vaginal introitus posterior Fourchette).....	____ ____ ____ . ____	no limit

Analysis Variable : POPQ_GH								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
883	8	2.9	1.0	0.5	2.0	3.0	3.5	8.0

D8.	**PB**	perineal body (vaginal introitus posterior Fourchette to mid-anal opening).....	____ ____ ____ . ____	no limit

Analysis Variable : POPQ_PB								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
883	8	3.7	1.0	1.0	3.0	4.0	4.0	7.0

EXAMPLE

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D9. **TVL** total vaginal length.....	____ ____ ____ . ____	no limit

Analysis Variable : POPQ_TVL								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
884	7	9.2	1.3	3.0	8.0	9.0	10.0	13.0

D10 Record Prolapse Stage: Stage 0 or I..... 1 [D2, D3, D6: all < -1]

.

Stage II or higher ..... 2 [D2, D3, D6: any ≥ -1]

Stage 0	Point Aa, Ap, Ba, & Bp are all at -3cm <u>and</u> either point C or D is at ≤ -(TVL-2) cm
Stage I	The criteria for Stage 0 are not met <u>and</u> the leading edge of prolapse is < -1 cm

Stage II	Leading edge of prolapse is ≥ -1 cm but ≤ +1 cm
Stage III	Leading edge of prolapse is > + 1 cm but < +(TVL-2) cm
Stage IV	Leading edge of prolapse is ≥ +(TVL-2) cm
TVL	Total vaginal length in centimeters in Stages O, III and IV.

PRO_STAGE	Frequency	Percent	Cum Freq	Cum Percent
.	8	.	.	.
1: Stage 0 or I	588	66.59	588	66.59
2: Stage II or higher	295	33.41	883	100.00

Frequency Missing = 8

SECTION E: PVR ASSESSMENT

E1. PVR: ___ ___ ___ mL

Analysis Variable : PVR								
N	N Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
878	13	34.7	46.0	0.0	2.0	20.0	49.0	450.0

E2. Assessed by which method? Catheterization..... 1 Bladder Scan..... 2 Calculated..... 3

PVR_METHOD	Frequency	Percent	Cum Freq	Cum Percent
.	12	.	.	.
1: Catheterization	342	38.91	342	38.91
2: Bladder Scan	537	61.09	879	100.00

Frequency Missing = 12

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SECTION F: MESH EXAM

F1. Is there any evidence of TOMUS surgery mesh exposure? Yes..... 1 ➔**COMPLETE FE91** No..... 2

MESH_EXPO	Frequency	Percent	Cum Freq	Cum Percent
.	1	.	.	.
1: Yes	17	1.91	17	1.91
2: No	873	98.09	890	100.00

Frequency Missing = 1

F2. Is there any evidence of TOMUS surgery mesh erosion? Yes..... 1 ➔**COMPLETE FE91** No..... 2

MESH_ERO	Frequency	Percent	Cum Freq	Cum Percent
.	1	.	.	.
1: Yes	4	0.45	4	0.45
2: No	886	99.55	890	100.00

Frequency Missing = 1

F3. Does patient have pain with the TOMUS surgery-related mesh AE? Yes..... 1 ⬇**SPECIFY** No..... 2 N/A 3

MESH_PAIN	Frequency	Percent	Cum Freq	Cum Percent
.	1	.	.	.
1: Yes	10	1.12	10	1.12
2: No	320	35.96	330	37.08
3: NA	560	62.92	890	100.00

Frequency Missing = 1

F3a. Specify

_____

F4. Examiner's Signature: _____ Examiner's Initials: ____ ____ ____

Date of Signature: ___ ___ / ___ ___ / ___ ___ ___ ___

Month Day Year

TOMUS