



F309: Randomization Assignment and Confirmation, version 04/10/06 (A)_rev06/01/06

Section A: General Study Information for Office Use Only:

A1. Study ID#:

A2. Visit # Randomization TRND

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

SECTION B: SOURCE DOCUMENT REVIEW ATTESTATION

B1. Initials of Interviewer/Data Collector who completed a thorough review of all source documents (i.e. inpatient medical records, clinic charts, etc.) to ensure eligibility: _____

B2. Date Review Completed: ___/___/___
Month Day Year

Analysis Variable : REVIEW_Daysnew								
N	Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
597	0	7.4	14.9	0.0	1.0	3.0	7.0	163.0

B3. Signature of Data Collector Completing B1: _____

SECTION C: PRE-SURGICAL ELIGIBILITY REQUIREMENTS

C1. Does the patient meet **all pre-surgical** eligibility requirements? YES 1
 NO 2 → **INELIGIBLE**

PRE_SURG	Frequency	Percent	Cum Freq	Cum Percent
1	597	100.00	597	100.00

C2. **Randomization authorization number:** _____

C2a. Expiration date: ___/___/___
Month Day Year

Analysis Variable : RAND_EXP_Days								
N	Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
597	0	130.6	36.3	0.0	115.0	140.0	156.0	178.0

C3. Initials of Data Collector completing Section C: _____

C3a. Signature of Data Collector completing Section C: _____

SIGN_SEC_C	Frequency	Percent	Cum Freq	Cum Percent
1	597	100.00	597	100.00

SECTION D: FINAL ELIGIBILITY DETERMINATION AND RANDOMIZATION

D1. Is the patient **ASA Class I, II or III** per anesthesiologist? YES 1
 NO 2 → **INELIGIBLE**

ASA_CLASS	Frequency	Percent	Cum Freq	Cum Percent
1	597	100.00	597	100.00

RANDOMIZATION TOLL-FREE TELEPHONE NUMBER: 1- 888- 216-1672
ACCESS CODE NUMBER FOR TOMUS TRIAL: 32551

D2. What is the date of randomization? _____ / _____ / _____
 Month Day Year

RAND_Days	Frequency	Percent	Cum Freq	Cum Percent
0	597	100.00	597	100.00

D3. What was the assignment by telephone? Retropubic 1
 Transobturator 2
 Could not (did not) randomize by phone 3 → **SKIP TO E1**

TELE_ASSIGN	Frequency	Percent	Cum Freq	Cum Percent
1	281	47.07	281	47.07
2	279	46.73	560	93.80
3	37	6.20	597	100.00

PLEASE WAIT FOR CONFIRMATION NUMBER BEFORE HANGING UP

D4. Randomization confirmation number: _____ → **SKIP TO E5**

SECTION E: DOCUMENTATION OF RANDOMIZATION DEVIATIONS

E1. Reason that the patient was not randomized by telephone:
 No access to telephone/Telephone not working 1
 Telephone randomization system not working 2
 Busy signal after 3 tries 3
 Other 4 → SPECIFY: _____

REASON	Frequency	Percent	Cum Freq	Cum Percent
-2	560	93.80	560	93.80
1	1	0.17	561	93.97
2	29	4.86	590	98.83
4	7	1.17	597	100.00

- E2. What was the assignment by envelope? Retropubic 1
Transobturator..... 2
Could not (did not) randomize by envelope 3 → SKIP TO E4

ENV_ASSIGN	Frequency	Percent	Cum Freq	Cum Percent
-2	560	93.80	560	93.80
1	17	2.85	577	96.65
2	20	3.35	597	100.00

- E3. Envelope Number: _____ →SKIP TO E5

Analysis Variable : ENV_NUM								
N	Miss	Mean	SD	Minimum	Lower Quartile	Median	Upper Quartile	Maximum
37	0	3.6	2.7	1.0	1.0	3.0	5.0	11.0

ENV_NUM	Frequency	Percent	Cum Freq	Cum Percent
-2	560	100.00	560	100.00

- E4. Why not? _____

WHY_NOT	Frequency	Percent	Cum Freq	Cum Percent
-2	597	100.00	597	100.00

- E5. Initials of Data Collector completing Sections D and E: _____

- E5a. Signature of Data Collector completing Sections D and E: _____