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#: Label								
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, etd.) to ensure eligibility: B2. Date Review Completed: Month Day Year Analysis Variable: REVIEN Daysnew N Miss Mean SD Minimum Quartile Median Quartile Maximum Spy No. 165.0 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 Nomth Day Year Analysis Variable: RAND EXP Days N Miss Mean SD Minimum Quartile Median 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:	Section A: General Study Information for Office Use Only:							
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C3a. Signature of Data Collector completing Section C:	C3a. Signature of Data C	ollector comple	eting Section	C:				

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

SECTION D: FINAL ELIGIBILITY DETERMINATION AND RANDOMIZATION YES..... 1 D1. Is the patient **ASA Class I, II or III** per anesthesiologist? NO..... 2 **→** INELIGIBLE ASA CLASS Cum Freq Cum Percent Frequency Percent 100.00 597 100.00 RANDOMIZATION TOLL-FREE TELEPHONE NUMBER: 1-888-216-1672 ACCESS CODE NUMBER FOR TOMUS TRIAL: 32551 What is the date of randomization? D2. Day Month Year RAND_Days Frequency Cum Freq Cum Percent Percent 597 100.00 597 100.00 What was the assignment by telephone? Retropubic 1 → SKIP TO E1 Could not (did not) randomize by phone 3 TELE ASSIGN Frequency Percent Cum Freq Cum Percent 281 47.07 281 47.07 279 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 SPECIFY: **REASON** Frequency Percent Cum Freq Cum Percent 560 93.80 93.80 -2 560

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1

29

1

2

4

0.17

4.86

1.17

561

590

597

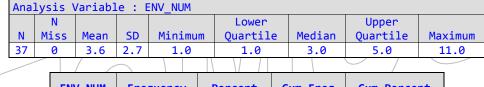
93.97

98.83

100.00

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



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:

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