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



Section A: General Study Information for Office Use Only:		
A1. Study ID#: Label	A2. Visit # RandomizationTRND	
A3. Date Form Completed://		
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 Year		
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	
C2. Randomization authorization number:		
C2a. Expiration date:/	ear	
C3. Initials of Data Collector completing Section C:		
C3a. Signature of Data Collector completing Section C:		
SECTION D: FINAL ELIGIBILITY DETERMINATION AND RANDOMIZATION		
D1. Is the patient ASA Class I, II or III per anesthesiologist?	YES	
RANDOMIZATION TOLL-FREE TELEPHONE NUMBER: 1- 888- 216-1672		
ACCESS CODE NUMBER FOR TOMUS TRIAL: 32551		
D2. What is the date of randomization?/	/	

D3.	What was the assignment by telephone?	Retropubic 1
		Transobturator
		Could not (did not) randomize by phone 3 → SKIP TO E1
	PLEASE WAIT FOR CONF	FIRMATION NUMBER BEFORE HANGING UP
D4.	Randomization confirmation number:	SKIP TO E5
SECTION E: DOCUMENTATION OF RANDOMIZATION DEVIATIONS		
E1.	Reason that the patient was not randomize No access to telephone/Telephone n	ot working 1
	Telephone randomization system no	
	Busy signal after 3 tries	
	Other	SPECIFY:
E2.	What was the assignment by envelope?	Retropubic 1
		Transobturator
		Could not (did not) randomize by envelope 3 → SKIP TO E4
E3.	Envelope Number: →s	KIP TO E5
E4.	Why not?	
E5.	Initials of Data Collector completing Secti	ons D and E:
E5a.	Signature of Data Collector completing Sec	etions D and E: