

F509: Randomization Assignment and Confirmation, version 09/08/08 (A)



Value

SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY

A1. Study ID#:

A2. Visit #: Randomization.....VRND

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

SECTION B: PRE-RANDOMIZATION ELIGIBILITY REQUIREMENTS

B1. Did the patient sign the Value consent form? Yes 1

No..... 2 → **INELIGIBLE FOR RANDOMIZATION**

CONSENT	Frequency	Percent	Cum Freq	Cum Percent
1: YES	630	100.00	630	100.00

B2. Does the patient meet all eligibility requirements per F500? Yes 1

No..... 2 → **INELIGIBLE FOR RANDOMIZATION**

ELIGIBILITY	Frequency	Percent	Cum Freq	Cum Percent
1: YES	630	100.00	630	100.00

B3. Initials of Study Staff attesting to eligibility on F500:
(i.e. person listed in A4 on F500) _____

B4. Primary Surgeon Initials: _____

B5. Initials of Study Staff completing Sections A and B: _____

SECTION C: DOCUMENTATION OF RANDOMIZATION

RANDOMIZATION TELEPHONE NUMBER: 1-888-216-1672

Value ACCESS CODE NUMBER: 51594

C1. Date of Randomization: ___/___/___
Month Day Year

- C2. What was the assignment by telephone? UDS..... 1
 No UDS..... 2
 Could not (did not) randomize by phone..... 3 → **SKIP TO D1**

TELE_ASSIGN	Frequency	Percent	Cum Freq	Cum Percent
1: UDS	315	50.00	315	50.00
2: No UDS	315	50.00	630	100.00

PLEASE WAIT FOR CONFIRMATION NUMBER BEFORE HANGING UP

C3. Randomization Confirmation Number: _____ ➔ **SKIP TO E1**

SECTION D: DOCUMENTATION OF RANDOMIZATION DEVIATIONS

D1. 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: _____

D2. What was the assignment by envelope? UDS 1

No UDS 2

Could not (did not) randomize by envelope 3 ➔ **SKIP TO D4**

D3. Envelope Number: _____ ➔ **SKIP TO E1**

D4. Why not? _____

SECTION E: SIGNATURE

E1. Signature of Study Staff completing randomization: _____

RAND_SIG N	Frequency	Percent	Cum Freq	Cum Percent
I: YES	630	100.00	630	100.00

E2. Initials of Study Staff completing randomization: _____

FOR REFERENCE: Numeric codes for entering initials when using the phone randomization system.

A=01	B=02	C=03	D=04	E=05	F=06	G=07
H=08	I=09	J=10	K=11	L=12	M=13	N=14
O=15	P=16	Q=17	R=18	S=19	T=20	U=21
V=22	W=23	X=24	Y=25	Z=26	Dash=00	

Example: ABC=010203