



SECTION A: GENERAL STUDY INFORMATION FOR OFFICE USE ONLY

A1. Study ID#:

LABEL

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

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

Yes ..... 1

No ..... 2 → INELIGIBLE FOR RANDOMIZATION

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

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: \_\_\_\_\_

E2. Initials of Study Staff completing randomization: \_\_\_\_\_

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

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

**Example: ABC=010203**