	SPI-611 #025 Informed Consent / Inclusion Criteria #001			
S	Site No. Randomization No. Patient Initials	SCI	REEN	ING
		F Code:	0	1
Vis	sit Date: DD MMM YYYY		U	1 1
IN	FORMED CONSENT			
Da	te Informed Consent Signed: DD MMM YYYY Screening ID:]
IN	CLUSION CRITERIA			
All	of the following questions must be answered "YES" or "N/A" in order for the patient to participat	e in the	study.	
		YES	NO	N/A
1.	Has the patient given written informed consent?			
2.	Is the patient at least 18 years old?			
3.	Does the patient have transitional cell carcinoma of the bladder with clinically apparent stage Ta, grade G1-G2?			
4.	If the patient is a female of childbearing potential, is she using an acceptable/effective method of contraception?			
5.	If the patient is a female of childbearing potential, has she had a negative serum pregnancy test within the past 14 days?			
6.	Is the patient willing and able to abide by the protocol?			

	SPI-611 #025 Exclusion Criteria #002		
; 	Site No. Randomization No. Patient Initials DF Cod	CREEN	ING
	XCLUSION CRITERIA of the following questions must be answered "NO" in order for the patient to participate in the study.	ie. <u>[U</u>	11
		YES	NO
1.	Does the patient have more than 4 bladder tumors?		
2.	Does any single bladder tumor exceed 3.5 cm in diameter?		
3.	Does the patient have a single, primary (no previous diagnosis of TCC) bladder tumor <0.5 cm?		
4.	Has the patient ever received EOquin [®] ?		
5.	Does the patient have, or has the patient ever had, any bladder tumor known to be other than stage Ta or grade G1 or G2 (low grade [WHO/ISUP classification])?		
6.	Does the patient have, or has the patient ever had, any bladder tumor with histology other than transitional cell carcinoma?		
7.	Does the patient have, or has the patient ever had, CIS?		
8.	Does the patient have an active urinary tract infection?		
9.	Does the patient have a bleeding disorder or a screening platelet count <100 x 10 ⁹ /L?		
10	. Does the patient have any unstable medical condition that would make it unsafe for him/her to undergo TUR-BT under general or spinal anesthesia?		
11.	Does the patient have a screening hemoglobin <10 mg/dL, a screening absolute neutrophil count <1.5 x 10^9 /L or a screening creatinine >2 mg/dL?		
12	. Does the patient have a known immunodeficiency disorder?		
13	. Has the patient received any investigational treatment within the past 30 days?		
14	. Is the patient breast feeding?		
15	. Does the patient have a history of interstitial cystitis?		
16	. Does the patient have a history of allergy to red color food dye?		
17	. Has the patient had transitional cell carcinoma of the bladder within the past 4 months?		

SPI-611 #02	Demographics / Smoking Status #003		
Site No. Ra	andomization No. Patient Initials	SCRI DF Code:	
DEMOGRA	PHICS		
Date of Birth:	DD MMM YYYY		
Sex:	☐ Male ☐ Female		
Ethnicity: (Mark "X" one)	Hispanic or Latino Not Hispanic or Latino		
Race: (Mark "X" all that apply)	American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander White		
SMOKING S	STATUS		
Smoking Status: (Mark "X" one)	☐ Current ☐ Former ☐ Never		

SPI-6	11 #025 Medical	History #004		
Site No.	Randomization No. Patient In	itials		SCREENING
			DF C	code: 0 1
			MH Pa	ge #: 0 1
MEDIC	AL HISTORY		Mark "X" if Last	MH Page:
	cord any previous illnesses, surgery imate date of onset (month and yea	or medical conditions in the	e space provided below. Plea	ase provide
Body	imate date of officer (month and yet	y or medical conditions in the ar). Notinal Abnormal		
System Code	Body System	Mour White	If ABNORMAL, Specify	/
0 1	EYES	- - <u> </u>		
02	EARS, NOSE, THROAT	- - <u> </u>		
0 3	RESPIRATORY			
0 4	CARDIOVASCULAR			
0 5	GASTROINTESTINAL			
06	MUSCULOSKELETAL	-		
0 7	SKIN	- - <u> </u>		
08	CNS/PSYCHIATRIC	- - <u> </u>		
09	ENDOCRINE	- - <u> </u>		
		<u> </u>		
	System Codes: 01 = Eyes 02 = Ears, Nose, Throat 03 = Respiratory	05 = Gastrointestinal 06 = Musculoskeletal 07 = Skin	08 = CNS/Psychiatric 09 = Endocrine 93 = Other	

SPI-611 #025 Bladder Cancer History #005		
Site No. Randomization No. Patient Initials	SCR	EENING
	DF Code:	0 1
BLADDER CANCER HISTORY		
Is the current tumor primary or recurrent bladder cancer?		
☐ Primary		
Recurrent, complete below:		
If RECURRENT, complete the following:		
Date of First Pathological Diagnosis of Bladder Cancer: DD MMM	YYYY	
Number of Previous Cystoscopies Positive for Bladder Cancer:		
Date of Last Occurrence: DD MMM YYYY		
Were any prior intravesical therapies administered? (Mark all that apply)		
BCG		
Mitomycin C		
Other, specify:		

SPI-611 #025	Vital Signs #006		
Site No. Rar	ndomization No. Patient Initials	SCR	EENING
		DF Code:	0 1
Visit Date:	DD MMM YYYY		
VITAL SIGNS	Mark "X" if Not Done		
Exam Date:	DD MMM YYYY		
Blood Pressure:	Systolic Diastolic mmHg		
Pulse:	beats/minute (bpm)		
Temperature:	°C		
Weight:	kg kg		

SPI-61	11 #025 Phy	vsical Exam #007	
Site No.	Randomization No. Pati	ent Initials	SCREENING
			DF Code: 0 1
PHYSIC	CAL EXAMINATION		PE Page #: 0 1
Exam Date	e: DD MMM	YYYY	Mark "X" if Last PE Page:
Body System Code	Body System	Mortral Abrormal Done	If ABNORMAL, Specify
0 1	SKIN		
02	EARS, NOSE, THROAT		
03	NECK/THYROID		
0 4	LUNGS		_
0 5	HEART		
06	ABDOMEN		
07	UROGENITAL		
08	LYMPH NODES		
09	NERVOUS SYSTEM		
	Body System Codes: 01 = Skin 02 = Ears, Nose, Throat 03 = Neck/Thyroid 04 = Lungs	05 = Heart 06 = Abdomen 07 = Urogenital	08 = Lymph Nodes 09 = Nervous System 93 = Other

DD

MMM

YYYY

SPI-611 #025 Laboratory Tests / Pregnancy Test #008		
Site No. Randomization No. Patient Initials	SCR	EENING
	DF Code:	0 1
LABORATORY TESTS		
Hematology Mark "X" if Not Done		
Collection Date: DD MMM YYYY		
Chemistry Mark "X" if Not Done		
Collection Date: DD MMM YYYY		
PREGNANCY TEST		
☐ Not Done, specify reason — ☐ Patient is male		
Patient is not of childbearing potential		
Other, specify:	_	
Collection Date:		

SPI-611 #025 Urine Dipstick / Urine	Cytology #009
Site No. Randomization No. Patient Initials	SCREENING
	DF Code: 0 1
URINE DIPSTICK	
Collection Date: DD MMM YYYY	
Test Result	
Specific Gravity	
pH	
Protein Negative Trace 1+	2+ 3+ 4+
Non-Hemolyzed	Hemolyzed
Blood Negative Trace Mode	rate Trace 1+ 2+ 3+
Glucose Negative 100 250	☐ 500 ☐ 1000 ☐ 2000 or more
Leukocyte	<u></u>
Nitrite	
If patient is leukocyte esterase or nitrite positive by urine analysis. Otherwise, do not send urine sample to central	
Microscopic Exam Mark "X" if Not Done	
Collection Date: DD MMM YYYY]
URINE CYTOLOGY	
Collection Date: DD MMM YYYY]

SPI-611 #025	Vital Signs #006	
Site No. Randomization No.	Patient Initials	VISIT 1: WEEK 0
		DF Code: 02
Visit Date: DD MMM	YYYY	
VITAL SIGNS	X" if Not Done	
Exam Date: DD MMM	YYYY	
Blood Pressure: // Systolic	/ mmHg Diastolic	
Pulse:	peats/minute (bpm)	
Temperature:] °C	

SPI-611 #025 Laboratory Tests / Pregnancy Test #008	
Site No. Randomization No. Patient Initials	VISIT 1: WEEK 0
	DF Code: 02
LABORATORY TESTS	

Hematology	Mark "X" i	f Not Done	
Collection Date:			
	DD	МММ	YYYY
Chemistry	Mark "X" if N	Not Done	
Collection Date:			
	DD	MMM	YYYY

SPI-611 #025	Urine Dipstick / Urine Cytology #009	
Site No. Rar	ndomization No. Patient Initials	VISIT 1: WEEK 0
		DF Code: 02
URINE DIPS	TICK Mark "X" if Not Done	
Collection Date:		
	DD MMM YYYY	Mark "X" if Abnormal and
Test	Result	Clinically Significant*
Specific Gravity		
рН		
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	
	Non-Hemolyzed Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate ☐ Trace ☐ 1+ ☐ 2+	□ 3+ □
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	
Nitrite	☐ Negative ☐ Positive	
	yte esterase or nitrite positive by urine dipstick, send urine sample to centra se, do not send urine sample to central lab.	al lab for microscopic
Microscopic Exa	m Mark "X" if Not Done	
Collection Date:		

^{*} If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.

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SPI-611 #025	Transure	ethral Resection	#010		
Site No. Randomization	on No. Patient In	iitials			VISIT 1: WEEK
					DF Code: 0 2
TRANSURETHRAL	RESECTIO	N			
Date of Surgery:	MMM	YYYY			
TUR Start Time:	(00:00-23:59)	TUR End	d Time:	(00:00-23:59)	
Total Number of Lesions:	If mo	ore than 4 lesio	ns, patient is	s ineligible (do not	instill study drug)
	Lesion # Lo	ocation Code		ze Diameter)	
	1.			_ cm	
	2.			_ cm	
	3.			_ cm	
	4.			_ cm	

Location Codes:

A = Anterior Wall

D = Dome L = Left Wall N = Neck of Bladder

P = Posterior Wall

R = Right Wall

T = Trigone

SPI-611 #025 Study Drug Instillation #012	I
Site No. Randomization No. Patient Initials	VISIT 1: WEEK 0 DF Code: 02
STUDY DRUG INSTILLATION	
Instillation Date: DD MMM YYYY	
Time Study Drug Instillation Began: (00:00-23:59)	
Time Study Drug Drained from Bladder: (00:00-23:59)	
Was the start of instillation within 6 hours from end of TUR?	
Yes No If NO, Give Reason:	
Volume of Instillate:	
☐ 40 mL	
Other, specify: mL	
If other than 40 mL, give reason:	
Was the study drug retained in bladder for 60 minutes?	
Yes	
No If NO, Give Reason:	
If NO, Duration of Retention: Minutes	

SPI-611 #025 Vital Signs #006	
Site No. Randomization No. Patient Initials	VISIT 2: WEEK 3 DF Code: 0 3
Visit Date: DD MMM YYYY	012
VITAL SIGNS	
Exam Date: DD MMM YYYY	
Blood Pressure: / mmHg Systolic Diastolic	
Pulse: beats/minute (bpm)	
Temperature: °C	

SPI-61 ⁻	1 #025 Pr	nysical Exam #007		
Site No.	Randomization No. Pat	ient Initials	VIS	SIT 2: WEEK 3
			DF C	ode: 0 3
PHYSIC	CAL EXAMINATION	(Brief)	PE Pag	e #: 0 1
Exam Date	DD MMM	YYYY	Mark "X" if Last	PE Page:
Body System Code	Body System LUNGS	Hornal Abhornal Done	If ABNORMAL, Specif	у
05	HEART			
06	ABDOMEN			
* If Clinica	lly Significant (change fro	m Baseline), documen	t relevant event on the Adverse Ever	ıts CRF.
	Body System Codes: 01 = Skin 02 = Ears, Nose, Throa 03 = Neck/Thyroid 04 = Lungs	05 = Heart 06 = Abdomen 07 = Urogenital	08 = Lymph Nodes 09 = Nervous System 93 = Other	

SPI-611 #025 Laboratory Tests / Pregnancy Test #008	
Site No. Randomization No. Patient Initials	VISIT 2: WEEK 3 DF Code: 0 3

LABORATORY TESTS

Hematology	Mark "X" if	Not Done			
Collection Date:					
	DD	MMM	YYYY		
Chemistry Mark "X" if Not Done					
Collection Date:					
	DD	MMM	YYYY		

SPI-611 #025	Urine Dipstick / Urine Cytology #009	
Site No. Rar	ndomization No. Patient Initials	VISIT 2: WEEK 3
		DF Code: 03
URINE DIPS	TICK Mark "X" if Not Done	
Collection Date:		
Test	DD MMM YYYY Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	-	
рН		
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	
	Non-Hemolyzed Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate ☐ Trace ☐ 1+ ☐ 2+	☐ 3+ ☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	
Nitrite	☐ Negative ☐ Positive	
	yte esterase or nitrite positive by urine dipstick, send urine sample to centr se, do not send urine sample to central lab.	al lab for microscopic
Microscopic Exar	m Mark "X" if Not Done	
Collection Date:		

^{*} If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.

SPI-611 #025	Pathology #011	
Site No. Randomization	n No. Patient Initials	VISIT 2: WEEK 3
		DF Code: 03
PATHOLOGY		
Report Date:	MMM YYYY	
Pathology Report Source: (Mark One)	Central Lab (Bostwick) Local Lab	
Highest pT S	Stage ^A :	
Highest Hist	ologic Grade ^B :	
Will patient receive additional	intravesical therapy (e.g. BCG, Mitomycin) for	bladder cancer based on this report?
Yes (Report therapy of	on Concomitant Medication CRF)	
□ No		

 A - pT Stage Codes:
 B - Histologic Grade Codes:

 1 = Ta
 3 = T2

 2 = T1
 4 = Cis

 2 = G2
 4 = Low Grade - WHO/ISUP

 5 = High Grade - WHO/ISUP

SPI-611 #025	Vital Signs #006	
Site No. Randomization N	No. Patient Initials	VISIT 3: MONTH 3
		DF Code: 0 4
Visit Date: DD MMM	M YYYY	
VITAL SIGNS Mai	rk "X" if Not Done	
Exam Date: DD MM	MM YYYY	
Blood Pressure: Systolic	/ mmHg Diastolic	
Pulse:	beats/minute (bpm)	
Temperature:	°C	

SPI-61	11 #025 P	hysical Exam #007		
Site No.	Randomization No. Pa	tient Initials	VISIT	Г 3: MONTH 3
			DF C	ode: 04
PHYSIC	CAL EXAMINATION	l (Brief)	PE Pag	ne #: 0 1
Exam Date	e: DD MMM	YYYY	Mark "X" if Last	PE Page:
Body System Code	Body System	Hornal Abnormat Done	If ABNORMAL, Specif	iy
0 4	LUNGS	_		
0 5	HEART			
06	ABDOMEN			
* If Clinica	ally Significant (change fro	om Baseline), documen	t relevant event on the Adverse Eve	nts CRF.
	Body System Codes: 01 = Skin 02 = Ears, Nose, Thro 03 = Neck/Thyroid 04 = Lungs	05 = Heart	08 = Lymph Nodes 09 = Nervous System 93 = Other	

Chemistry

Collection Date:

☐ Mark "X" if Not Done

MMM

SPI-611 #025	Laboratory Tests / Pregnancy Test #008		
Site No. Randomization No.	Patient Initials	VISIT 3: MON	TH 3
		DF Code:) 4
LABORATORY TESTS			
Hematology Mark "X" if Not	t Done		
Collection Date:			
DD MN	MM YYYY		

SPI-611 #025	Urine Dipstick / Urine Cytology #009	
Site No. Rar	ndomization No. Patient Initials	VISIT 3: MONTH 3
		DF Code: 0 4
URINE DIPS	TICK Mark "X" if Not Done	
Collection Date:		
Test	DD MMM YYYY Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity		
рН		
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	
	Non-Hemolyzed Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate ☐ Trace ☐ 1+ ☐ 2+	☐ 3+ ☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	e 🗆
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	
Nitrite	☐ Negative ☐ Positive	
	yte esterase or nitrite positive by urine dipstick, send urine sample to centrise, do not send urine sample to central lab.	al lab for microscopic
Microscopic Exar	m Mark "X" if Not Done	
Collection Date:		

^{*} If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.

SPI-611 #025 Cystoscopy #013		
Site No. Randomization No. Patient Initials	VISIT 3: N	ONTH 3
	DF Code:	0 4
CYSTOSCOPY		
Exam Date: DD MMM YYYY		
Is the site of initial TUR re-epithelialized?		
Were any tumors seen?		
If YES, were any biopsies performed?		
Yes If YES, enter location from code list below:		
No If NO, explain:		
Were any other abnormalities seen?		
Yes If YES, explain:		
□ No		

 $\begin{array}{ll} A = \text{Anterior Wall} & N = \text{Neck of Bladder} & R = \text{Right Wall} \\ D = \text{Dome} & P = \text{Posterior Wall} & T = \text{Trigone} \\ \end{array}$

SPI-611 #025 Vital Signs #006	
Site No. Randomization No. Patient Initials	VISIT 4: MONTH 6
	DF Code: 0 5
Visit Date: DD MMM YYYY	
VITAL SIGNS	
Exam Date: DD MMM YYYY	
Blood Pressure: / mmHg Systolic Diastolic	
Pulse: beats/minute (bpm)	
Temperature: °C	

SPI-61	1 #025 Ph	ysical Exam #007		
Site No.	Randomization No. Pat	ient Initials	VISIT	7 4: MONTH 6
			DF C	ode: 0 5
PHYSIC	CAL EXAMINATION	(Brief)	PE Pag	e #: 0 1
Exam Date	e: DD MMM	YYYY	Mark "X" if Last	PE Page:
Body System Code	Body System LUNGS	Hornal Abhornal Done	If ABNORMAL, Specif	y
05	HEART			
06	ABDOMEN			
* If Clinica	lly Significant (change fro	m Baseline), documen	t relevant event on the Adverse Evel	nts CRF.
	Body System Codes: 01 = Skin 02 = Ears, Nose, Throa 03 = Neck/Thyroid 04 = Lungs	05 = Heart 06 = Abdomen 07 = Urogenital	08 = Lymph Nodes 09 = Nervous System 93 = Other	

SPI-611 #025 Urine Dipstick / Urine Cytology #009	
Site No. Randomization No. Patient Initials	VISIT 4: MONTH 6
	DF Code: 0 5
URINE DIPSTICK Mark "X" if Not Done	
Collection Date: DD MMM YYYY	
Test Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	
рН	
Protein Negative Trace 1+ 2+ 3+ 4+	
Non-Hemolyzed Hemolyzed	
Blood Negative Trace Moderate Trace 1+ 2+	□ 3+ □
Glucose Negative 100 250 500 1000 2000 or mor	те 🔲
Leukocyte	
Nitrite	
If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to cent analysis. Otherwise, do not send urine sample to central lab.	ral lab for microscopic
Microscopic Exam Mark "X" if Not Done	
Collection Date: DD MMM YYYY	
URINE CYTOLOGY	
Collection Date:	

^{*} If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.

SPI-611 #025 Cystoscopy #013		
Site No. Randomization No. Patient Initials	ISIT 4: N	IONTH 6
	DF Code:	0 5
CYSTOSCOPY		
Exam Date: DD MMM YYYY		
Were any tumors seen?		
If YES, were any biopsies performed?		
Yes If YES, enter location from code list below:		
No If NO, explain:		
Were any other abnormalities seen?		
Yes If YES, explain:		
□ No		

 $\begin{array}{ll} A = \text{Anterior Wall} & N = \text{Neck of Bladder} & R = \text{Right Wall} \\ D = \text{Dome} & P = \text{Posterior Wall} & T = \text{Trigone} \\ \end{array}$

SPI-611 #025 Vital Signs #0	006	
Site No. Randomization No. Patient Initials	VISIT 5: MONTH	9
	DF Code: 0 6	
Visit Date: DD MMM YYYY		
VITAL SIGNS		
Exam Date: DD MMM YYYY		
Blood Pressure: / / / / / / / / / / / / / / / / / / /	mmHg	
Pulse: beats/minute (bp	om)	
Temperature: °C		

SPI-6		ysical Exam #007		
Site No.	Randomization No. Pati	ent Initials	VISIT 5	5: MONTH 9
			DF Cod	de: 06
PHYSI	CAL EXAMINATION	(Brief)	PE Page :	#: 01
Exam Date	e: DD MMM	YYYY	Mark "X" if Last PE	Page:
Body System Code	Body System	Hornal Abrornat Done	If ABNORMAL, Specify	
0 4	LUNGS			
0 5	HEART			
06	ABDOMEN			
* If Clinica	ally Significant (change from	m Baseline), document	relevant event on the Adverse Events	CRF.
	Body System Codes: 01 = Skin 02 = Ears, Nose, Throa 03 = Neck/Thyroid 04 = Lungs	05 = Heart t 06 = Abdomen 07 = Urogenital	08 = Lymph Nodes 09 = Nervous System 93 = Other	

SPI-611 #025	Urine Dipstick / Urine Cytology #009	
Site No. Rar	ndomization No. Patient Initials	VISIT 5: MONTH 9
		DF Code: 06
URINE DIPS	TICK Mark "X" if Not Done	
Collection Date:		
Test	DD MMM YYYY Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity		
рН		
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	
	Non-Hemolyzed Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate ☐ Trace ☐ 1+ ☐ 2+	3+
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	
Nitrite	☐ Negative ☐ Positive	
	yte esterase or nitrite positive by urine dipstick, send urine sample to centrise, do not send urine sample to central lab.	al lab for microscopic
Microscopic Exar	m Mark "X" if Not Done	
Collection Date:		

^{*} If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.

SPI-611 #025 Cystoscopy #013		
Site No. Randomization No. Patient Initials	VISIT 5: N	MONTH 9
	DF Code:	0 6
CYSTOSCOPY		
Exam Date: DD MMM YYYY		
Were any tumors seen?		
If YES, were any biopsies performed?		
Yes If YES, enter location from code list below:		
No If NO, explain:		
Were any other abnormalities seen?		
Yes If YES, explain:		
□ No		

 $\begin{array}{ll} A = Anterior \ Wall & N = Neck \ of \ Bladder & R = Right \ Wall \\ D = Dome & P = Posterior \ Wall & T = Trigone \\ \end{array}$

SPI-611 #025 Vital Signs #006	
Site No. Randomization No. Patient Initials	VISIT 6: MONTH 12
	DF Code: 0 7
Visit Date: DD MMM YYYY	
VITAL SIGNS	
Exam Date: DD MMM YYYY	
Blood Pressure: / mmHg Systolic Diastolic	
Pulse: beats/minute (bpm)	
Temperature: °C	

SPI-61	1 #025 Phy	ysical Exam #007		
Site No.	Randomization No. Pati	ent Initials	VISIT 6	6: MONTH 12
			DF Co	ode: 0 7
PHYSIC	CAL EXAMINATION	(Brief)	PE Page	e #: 0 1
Exam Date	DD MMM	YYYY	Mark "X" if Last F	'E Page:
Body System Code	Body System	Hornal Abrormat Done	If ABNORMAL, Specify	r
0 4	LUNGS			
0 5	HEART			
06	ABDOMEN			
* If Clinica	lly Significant (change fron	n Baseline), document	relevant event on the Adverse Even	ts CRF.
	Body System Codes: 01 = Skin 02 = Ears, Nose, Throat 03 = Neck/Thyroid 04 = Lungs	05 = Heart t 06 = Abdomen 07 = Urogenital	08 = Lymph Nodes 09 = Nervous System 93 = Other	

SPI-611 #025 Ur	rine Dipstick / Urine Cytology #009	
Site No. Randomization No. Pat	tient Initials VISIT	Γ 6: MONTH 12
	DF	Code: 0 7
URINE DIPSTICK	x "X" if Not Done	
Collection Date: DD MMM	YYYY	
Test Result		X" if Abnormal and ically Significant*
Specific Gravity		
рН		
Protein Negative	Trace 1+ 2+ 3+ 4+	
	Non-Hemolyzed Hemolyzed	
Blood Negative	Trace Moderate Trace 1+ 2+ 3+	
Glucose Negative	100	
Leukocyte	Trace 1+ 2+ 3+	
Nitrite Negative	Positive	
If patient is leukocyte esterase or nitrite analysis. Otherwise, do not send urine	e positive by urine dipstick, send urine sample to central lab for sample to central lab.	r microscopic
Microscopic Exam Mark "X" if	Not Done	
Collection Date: DD MMM	YYYY	
URINE CYTOLOGY M	lark "X" if Not Done	
Collection Date: DD MMM	YYYY	

^{*} If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.

SPI-611 #025 Cystoscopy #013		
Site No. Randomization No. Patient Initials	VISIT 6: M	ONTH 12
	DF Code:	0 7
CYSTOSCOPY		
Exam Date: DD MMM YYYY		
Were any tumors seen?		
If YES, were any biopsies performed?		
Yes If YES, enter location from code list below:]	
No If NO, explain:		
Were any other abnormalities seen?		
Yes If YES, explain:		
□ No		

 $\begin{array}{ll} A = \text{Anterior Wall} & N = \text{Neck of Bladder} & R = \text{Right Wall} \\ D = \text{Dome} & P = \text{Posterior Wall} & T = \text{Trigone} \\ \end{array}$

SPI-611 #025 Vital S	Signs #006	
Site No. Randomization No. Patient	nt Initials VISIT 7: MC	ONTH 15
	DF Code:	0 8
Visit Date: DD MMM	YYYY	
VITAL SIGNS	t Done	
Exam Date: DD MMM	YYYY	
Blood Pressure: / / / / / / / / / / / / / / / / / / /	mmHg stolic	
Pulse: beats/min	inute (bpm)	
Temperature: °C		

SPI-61 ²	1 #025 Ph	ysical Exam #007		
Site No.	Randomization No. Pati	ent Initials	VISIT	7: MONTH 15
			DF Co	ode: 0 8
PHYSIC	CAL EXAMINATION	(Brief)	PE Page	e #: 0 1
Exam Date	DD MMM	YYYY	Mark "X" if Last F	PE Page:
Body System Code	Body System	Hornal Abrornal Done	If ABNORMAL, Specify	,
0 4	LUNGS			
0 5	HEART			
06	ABDOMEN			
* If Clinical	lly Significant (change from	n Baseline), document	relevant event on the Adverse Even	ts CRF.
	Body System Codes: 01 = Skin 02 = Ears, Nose, Throa 03 = Neck/Thyroid 04 = Lungs	05 = Heart t 06 = Abdomen 07 = Urogenital	08 = Lymph Nodes 09 = Nervous System 93 = Other	

SPI-611 #025	Urine Dipstick / Urine Cytology #009	
Site No. Ran	domization No. Patient Initials	VISIT 7: MONTH 15
		DF Code: 08
URINE DIPS	TICK Mark "X" if Not Done	
Collection Date:		
_	DD MMM YYYY	Mark "X" if Abnormal and
Test	Result	Clinically Significant*
Specific Gravity		
рН		
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	
	Non-Hemolyzed Hemolyzed	
Blood	Negative Trace Moderate Trace 1+ 2+	□ 3+ □
Glucose	Negative □ 100 □ 250 □ 500 □ 1000 □ 2000 or more	
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	
Nitrite	☐ Negative ☐ Positive	
	yte esterase or nitrite positive by urine dipstick, send urine sample to central, do not send urine sample to central lab.	al lab for microscopic
Microscopic Exam	n Mark "X" if Not Done	
Collection Date:		

^{*} If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.

SPI-611 #025 Cystoscopy #013	
Site No. Randomization No. Patient Initials VISIT 7	7: MONTH 15
DF Co	ode: 08
CYSTOSCOPY	
Exam Date: DD MMM YYYY	
Were any tumors seen?	
If YES, were any biopsies performed?	
Yes If YES, enter location from code list below:	
No If NO, explain:	
Were any other abnormalities seen?	
Yes If YES, explain:	
□ No	

 $\begin{array}{ll} A = Anterior \ Wall & N = Neck \ of \ Bladder & R = Right \ Wall \\ D = Dome & P = Posterior \ Wall & T = Trigone \\ \end{array}$

SPI-611 #025 Vital Signs #006	
Site No. Randomization No. Patient Initials	VISIT 8: MONTH 18
	DF Code: 09
Visit Date: DD MMM YYYY	
VITAL SIGNS	
Exam Date: DD MMM YYYY	
Blood Pressure: / mmHg Systolic Diastolic	
Pulse: beats/minute (bpm)	
Temperature: °C	

SPI-611	1 #025 Ph	ysical Exam #007		
Site No.	Randomization No. Pati	ent Initials	VISIT 8	3: MONTH 18
			DF Co	ode: 0 9
PHYSIC	CAL EXAMINATION	(Brief)	PE Page	e #: 0 1
Exam Date:	: DD MMM	YYYY	Mark "X" if Last F	PE Page:
Body System Code	Body System	Hornal Abnormat Done	If ABNORMAL, Specify	,
0 4	LUNGS			
0 5	HEART			
06	ABDOMEN			
* If Clinical	lly Significant (change fron	n Baseline), document	relevant event on the Adverse Even	ts CRF.
	Body System Codes: 01 = Skin 02 = Ears, Nose, Throat 03 = Neck/Thyroid 04 = Lungs	05 = Heart 06 = Abdomen 07 = Urogenital	08 = Lymph Nodes 09 = Nervous System 93 = Other	

SPI-611 #025 Urine Dipstick / Urine Cytology #009	
Site No. Randomization No. Patient Initials	VISIT 8: MONTH 18
	DF Code: 09
URINE DIPSTICK	
Collection Date: DD MMM YYYY	
Test Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	
pH	
Protein Negative Trace 1+ 2+ 3+ 4+	
Non-Hemolyzed Hemolyzed	
Blood Negative Trace Moderate Trace 1+	☐ 2+ ☐ 3+ ☐
Glucose	0 or more
Leukocyte	
Nitrite	
If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample analysis. Otherwise, do not send urine sample to central lab.	e to central lab for microscopic
Microscopic Exam Mark "X" if Not Done	
Collection Date: DD MMM YYYY	
URINE CYTOLOGY	
DD MMM YYYY	

^{*} If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.

SPI-611 #025	Cystoscopy #013			
Site No. Randomization No.	Patient Initials		VISIT 8: M	ONTH 18
			DF Code:	09
CYSTOSCOPY				
Exam Date: DD MMM	YYYY			
Were any tumors seen?	s 🔲 No			
If YES, were any biopsies perfo	ormed?	Location		
Yes If YES, enter loc	cation from code list below:	Location:		
☐ No If NO, explain:				
Were any other abnormalities seen	?			
Yes If YES, explain:				
□ No				

 $\begin{array}{ll} A = \mbox{Anterior Wall} & N = \mbox{Neck of Bladder} & R = \mbox{Right Wall} \\ D = \mbox{Dome} & P = \mbox{Posterior Wall} & T = \mbox{Trigone} \\ \end{array}$

SPI-611 #025 Vital Signs #006	
Site No. Randomization No. Patient Initials	VISIT 9: MONTH 21
	DF Code: 1 0
Visit Date: DD MMM YYYY	
VITAL SIGNS	
Exam Date: DD MMM YYYY	
Blood Pressure: / mmHg Systolic Diastolic	
Pulse: beats/minute (bpm)	
Temperature: °C	

 SPI-61	1 #025 Ph	ysical Exam #007	
Site No.	Randomization No. Pati	ent Initials	VISIT 9: MONTH 21 DF Code: 1 0
PHYSIC	CAL EXAMINATION	(Brief)	PE Page #: 0 1
Exam Date	e: DD MMM	YYYY	Mark "X" if Last PE Page:
Body System Code	Body System LUNGS	Normal Abnormal Done	If ABNORMAL, Specify
0 5	HEART		
06	ABDOMEN		
* If Clinica	ally Significant (change from	m Baseline), document	relevant event on the Adverse Events CRF.
	Body System Codes: 01 = Skin 02 = Ears, Nose, Throa 03 = Neck/Thyroid 04 = Lungs	05 = Heart t 06 = Abdomen 07 = Urogenital	08 = Lymph Nodes 09 = Nervous System 93 = Other

SPI-611 #025	Urine Dipstick / Urine Cytology #009	
Site No. Rar	ndomization No. Patient Initials	VISIT 9: MONTH 21
		DF Code: 10
URINE DIPS	TICK Mark "X" if Not Done	
Collection Date:		
Test	DD MMM YYYY Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity		
рН		
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	
	Non-Hemolyzed Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate ☐ Trace ☐ 1+ ☐ 2+	□ 3+ □
Glucose	Negative □ 100 □ 250 □ 500 □ 1000 □ 2000 or more	е 🔲
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	
Nitrite	☐ Negative ☐ Positive	
	yte esterase or nitrite positive by urine dipstick, send urine sample to centrise, do not send urine sample to central lab.	al lab for microscopic
Microscopic Exar	m Mark "X" if Not Done	
Collection Date:		

^{*} If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.

SPI-611 #025 Cystoscopy #013	
Site No. Randomization No. Patient Initials	VISIT 9: MONTH 21
	DF Code: 10
CYSTOSCOPY	
Exam Date: DD MMM YYYY	
Were any tumors seen?	
If YES, were any biopsies performed?	
Yes If YES, enter location from code list below:	
☐ No If NO, explain:	
Were any other abnormalities seen?	
Yes If YES, explain:	
□ No	

 $\begin{array}{ll} A = \mbox{Anterior Wall} & N = \mbox{Neck of Bladder} & R = \mbox{Right Wall} \\ D = \mbox{Dome} & P = \mbox{Posterior Wall} & T = \mbox{Trigone} \\ \end{array}$

SPI-611 #025	Vital Signs #006	
Site No. Randomization N Visit Date:	lo. Patient Initials	VISIT 10: MONTH 24 DF Code: 1 1
VITAL SIGNS Mari	k "X" if Not Done	
Blood Pressure: Systolic	/ YYYY mmHg Diastolic	
Pulse:	beats/minute (bpm)	
Temperature:	°C	

SPI-61	1 #025 Phy	ysical Exam #007		
Site No.	Randomization No. Pation	ent Initials	VISIT 10:	MONTH 24
			DF Cod	e: 111
PHYSIC	CAL EXAMINATION	(Brief)	PE Page #	#: 01
Exam Date	DD MMM	YYYY	Mark "X" if Last PE	Page:
Body System Code	Body System	Hornal Abnormat Done	If ABNORMAL, Specify	
0 4	LUNGS			
0 5	HEART			
06	ABDOMEN			
* If Clinica	nlly Significant (change fron	n Baseline), document	relevant event on the Adverse Events	CRF.
	Body System Codes: 01 = Skin 02 = Ears, Nose, Throat 03 = Neck/Thyroid 04 = Lungs	05 = Heart 06 = Abdomen 07 = Urogenital	08 = Lymph Nodes 09 = Nervous System 93 = Other	

SPI-611 #025	Urine Dipstick / Urine Cytology #009	
Site No. Randomization No. P	- attent mittals	IT 10: MONTH 24 DF Code: 1 1
URINE DIPSTICK Ma	ark "X" if Not Done	
Collection Date:		
Test Result Specific Gravity	Mar	rk "X" if Abnormal and Slinically Significant*
pH		
Protein Negative	☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	
□ Nogativo □	Non-Hemolyzed Hemolyzed Trace Moderate Trace 1+ 2+	3+ □
Blood Negative Clucose Negative	☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	»+ ⊔ □
Leukocyte		
Nitrite Negative	Positive	
If patient is leukocyte esterase or nitr analysis. Otherwise, do not send urin	rite positive by urine dipstick, send urine sample to central lal ne sample to central lab.	o for microscopic
Microscopic Exam	if Not Done	
Collection Date: DD MMM	M YYYY	
URINE CYTOLOGY	Mark "X" if Not Done	
Collection Date:		

^{*} If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.

SPI-611 #025	Cystoscopy #013			
Site No. Randomization No.	Patient Initials		VISIT 10: MO	ONTH 24
			DF Code:	1 1
CYSTOSCOPY				
Exam Date: DD MMM	YYYY			
Were any tumors seen? Ye	es 🗌 No			
If YES, were any biopsies perf	ormed?	Location:		
Yes If YES, enter lo	ocation from code list below:			
☐ No If NO, explain:				
Were any other abnormalities see	n?			
Yes If YES, explain: _				
□ No				

 $\begin{array}{ll} A = \mbox{Anterior Wall} & N = \mbox{Neck of Bladder} & R = \mbox{Right Wall} \\ D = \mbox{Dome} & P = \mbox{Posterior Wall} & T = \mbox{Trigone} \\ \end{array}$

SPI-611 #025 End of Study #099
Site No. Randomization No. Patient Initials
END OF STUDY
Date of Termination: DD MMM YYYY
Did the patient complete the study through Year 2?
If NO, did the patient experience an AE that caused them to discontinue the study?
If YES, AE <u>primarily</u> responsible for discontinuing the study:
AE Page #: AE #:
If NO, mark one of the following:
Patient Withdrew Consent
Patient Refuses Follow-up Cystoscopy
Patient Lost to Follow-up or does not Comply with Protocol
Sponsor Decision
Investigator Decision
Other, specify:

SPI-611 #025 Investigator Signatur	re #100
Site No. Randomization No. Patient Initials	
INVESTIGATOR SIGNATURE	
To be completed only after the data in this CRF have bee	n reviewed, corrected and accepted.
I have reviewed the forms and the data collected are,	to the best of my knowledge, correct.
	Date:
Principal Investigator's Signature	DD MMM YYYY
Printed Name of Principal Investigator	

	SPI-611 #025	Adverse Events #097		
	te No. Randomization N	o. Patient Initials		AE Page #: 0 1 Mark "X" if Last AE Page:
	VERSE EVENTS Mark "X" if No Adverse Ever	nts		
	ect all Adverse Events through icipation in the study.	gh Visit 4 (6 Months). Collect ç	genitourinary Adverse	Events for the patient's entire
1.	Adverse Event Term:			
	Start Date: DD	MMM YYYY	Stop Date:	D MMM YYYY
	Serious?	Toxicity Grade	Relationship to Study Drug	Outcome
	 Yes (Notify Sponsor) No	☐ 1-Mild☐ 2-Moderate	UnrelatedUnlikely	Persisted at end of study
	NO	3-Severe	Possible	☐ Resolved with sequelae☐ Resolved without sequelae
		4-Life threatening 5-Fatal	Probable Definite	Death (If caused by this AE)
2.	Adverse Event Term:			
	Start Date:	MMM YYYY	Stop Date:	D MMM YYYY
	Serious?	Toxicity Grade	Relationship to Study Drug	Outcome
	Yes (Notify Sponsor)	1-Mild	Unrelated	Persisted at end of study
	☐ No	2-Moderate	Unlikely	Resolved with sequelae
		3-Severe	Possible	Resolved without sequelae
		4-Life threatening	☐ Probable	Death (If caused by this AE)
		5-Fatal	Definite	

	SPI-611 #025	Adverse Events #097	1 ■	
AD Colle			genitourinary Adver	AE Page #: 02 Mark "X" if Last AE Page: se Events for the patient's entire
parti	cipation in the study. Adverse Event Term:			
	Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)
2.	Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)

	SPI-611 #025	Adverse Events #097	1 ■	
AD	Randomization N VERSE EVENTS ect all Adverse Events throu		genitourinary Adver	AE Page #: 03 Mark "X" if Last AE Page:
parti	cipation in the study. Adverse Event Term:			
	Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)
2.	Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)

	SPI-611 #025	Adverse Events #097	1 ■	
AD Coll			genitourinary Adver	AE Page #: 0 4 Mark "X" if Last AE Page:
parti	cipation in the study. Adverse Event Term:			
	Start Date:	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)
2.	Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)

	SPI-611 #025	Adverse Events #097	1 ■	
AD Coll	Randomization N VERSE EVENTS ect all Adverse Events throught in the study.		genitourinary Adver	AE Page #: 05 Mark "X" if Last AE Page:
1.	Adverse Event Term: Start Date:		Stop Date:	
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)
2.	Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)

	SPI-611 #025	Adverse Events #097		
	te No. Randomization No	o. Patient Initials		AE Page #: 06
	ect all Adverse Events throug cipation in the study.	gh Visit 4 (6 Months). Collect ç	genitourinary Adver	se Events for the patient's entire
1.	Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)
2.	Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)

SPI-611 #025	Adverse Events #097		
Site No. Randomization N	lo. Patient Initials		AE Page #: 0 7
ADVERSE EVENTS			Mark "X" if Last AE Page:
Collect all Adverse Events throuparticipation in the study.	ugh Visit 4 (6 Months). Collect	genitourinary Advers	se Events for the patient's entire
1. Adverse Event Term:			
Start Date:	MMM YYYY	Stop Date:	DD MMM YYYY
Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)
2. Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)

	SPI-611 #025	Adverse Events #097	1 ■	
AD Coll	Randomization N VERSE EVENTS ect all Adverse Events throuse icipation in the study.		genitourinary Adver	AE Page #: 08 Mark "X" if Last AE Page:
1.	Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)
2.	Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)

	SPI-611 #025	Adverse Events #097	1 ■	
AD Colle			genitourinary Adver	AE Page #: 0 9 Mark "X" if Last AE Page:
1.	Adverse Event Term:			
	Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)
2.	Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)

	SPI-611 #025	Adverse Events #097	1 ■	
AD Coll			genitourinary Adver	AE Page #: 10 Mark "X" if Last AE Page:
parti	cipation in the study. Adverse Event Term:			
	Start Date:	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)
2.	Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)

SPI-611 #025 Concomitant Medications	4 098
Site No. Randomization No. Patient Initials	CM Page: 0 1
CONCOMITANT MEDICATIONS Mark "X" if No Concomitant Medications List all medications taken at Week 0 and through Visit 4 (Month Serious Adverse Events throughout the study.	Mark "X" if Last CM Page: 6). List medications taken for GU Adverse Events and
1. Name of Drug:	
Total Daily Dose: Units: Was medication taken for AE? Yes No If YES, primary AE Page #: AE #: If NO, record indication: 2. Name of Drug:	Start Date DD MMM YYYY Stop Date Continuing DD MMM YYYY
Total Daily Dose: Was medication taken for AE? Yes No If YES, primary AE Page #: AE #: If NO, record indication:	Start Date DD MMM YYYY Stop Date Continuing DD MMM YYYY
Total Daily Dose: Units: Was medication taken for AE? Yes No If YES, primary AE Page #: AE #:	Start Date DD MMM YYYY Stop Date Continuing
If NO, record indication:	DD MMM YYYY

SPI-611 #025 Concomitant Medications #	1 1098
Site No. Randomization No. Patient Initials	CM Page: $\boxed{0}$ $\boxed{2}$ Mark "X" if Last CM Page: \Box
CONCOMITANT MEDICATIONS	mant / ii Zact e.ii i age.
List all medications taken at Week 0 and through Visit 4 (Month Serious Adverse Events throughout the study.	6). List medications taken for GU Adverse Events and
1. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE?	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY
2. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? Yes No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY
3. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? Yes No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY

SPI-611 #025 Concomitant Medications #	# 098
Site No. Randomization No. Patient Initials	CM Page: 03
CONCOMITANT MEDICATIONS	Mark "X" if Last CM Page:
List all medications taken at Week 0 and through Visit 4 (Month Serious Adverse Events throughout the study.	6). List medications taken for GU Adverse Events and
1. Name of Drug:	
Total Daily Dose: Units: Was medication taken for AE?	Start Date DD MMM YYYYY Stop Date Continuing DD MMM YYYYY
2. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? ☐ Yes ☐ No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY
3. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? Yes No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY

SPI-611 #025 Concomitant Medications #	1 1098
Site No. Randomization No. Patient Initials	CM Page: $\boxed{0}$ $\boxed{4}$ Mark "X" if Last CM Page: \Box
CONCOMITANT MEDICATIONS	a A ii Zaat eiii i age.
List all medications taken at Week 0 and through Visit 4 (Month Serious Adverse Events throughout the study.	6). List medications taken for GU Adverse Events and
1. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE?	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY
2. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE?	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY
3. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE?	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY

SPI-611 #025 Concomitant Medications #	‡ 098
Site No. Randomization No. Patient Initials	CM Page: $\boxed{0\ 5}$ Mark "X" if Last CM Page: \Box
CONCOMITANT MEDICATIONS	
List all medications taken at Week 0 and through Visit 4 (Month Serious Adverse Events throughout the study. 1. Name of Drug:	6). List medications taken for GU Adverse Events and
	Start Date
Was medication taken for AE? Yes No If YES, primary AE Page #: AE #: If NO, record indication:	Start Date DD MMM YYYY Stop Date Continuing DD MMM YYYY
2. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? Yes No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY
3. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? Yes No	DD MMM YYYY
If YES, primary AE Page #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY

SPI-611 #025 Concomitant Medications #	4 098
Site No. Randomization No. Patient Initials	CM Page: $\boxed{0}$ $\boxed{6}$ Mark "X" if Last CM Page: \Box
CONCOMITANT MEDICATIONS	
List all medications taken at Week 0 and through Visit 4 (Month Serious Adverse Events throughout the study.	6). List medications taken for GU Adverse Events and
1. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? Yes No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY
2. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? Yes No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY
3. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? Yes No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY

SPI-611 #025 Concomitant Medications	4 098
Site No. Randomization No. Patient Initials	CM Page: $\boxed{0\ 7}$ Mark "X" if Last CM Page: \Box
CONCOMITANT MEDICATIONS	
List all medications taken at Week 0 and through Visit 4 (Month Serious Adverse Events throughout the study. 1. Name of Drug:	6). List medications taken for GU Adverse Events and
Total Daily Dose: Units:	Start Date
Was medication taken for AE? Yes No If YES, primary AE Page #: AE #:	DD MMM YYYY Stop Date Continuing
If NO, record indication:	DD MMM YYYY
2. Name of Drug: Total Daily Dose: Was medication taken for AE? Yes No If YES, primary AE Page #: AE #: If NO, record indication:	Start Date DD MMM YYYY Stop Date Continuing DD MMM YYYY
3. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? ☐ Yes ☐ No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY

SPI-611 #025 Concomitant Medications	4 4098
Site No. Randomization No. Patient Initials	CM Page: $\boxed{0\ 8}$
CONCOMITANT MEDICATIONS List all medications taken at Week 0 and through Visit 4 (Month Serious Adverse Events throughout the study. 1. Name of Drug: Total Daily Dose: Was medication taken for AE? Yes No If YES, primary AE Page #: AE #: If NO, record indication: 2. Name of Drug:	
Total Daily Dose: Units: Was medication taken for AE?	Start Date DD MMM YYYY Stop Date Continuing DD MMM YYYY
Total Daily Dose: Was medication taken for AE? Yes No If YES, primary AE Page #: AE #:	Start Date DD MMM YYYY Stop Date Continuing DD MMM YYYY

SPI-611 #025 Concomitant Medications #	4 098
Site No. Randomization No. Patient Initials	CM Page: $\boxed{0}$ $\boxed{9}$ Mark "X" if Last CM Page: \Box
CONCOMITANT MEDICATIONS	
List all medications taken at Week 0 and through Visit 4 (Month Serious Adverse Events throughout the study.	6). List medications taken for GU Adverse Events and
1. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? Yes No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY
2. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? ☐ Yes ☐ No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY
3. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? Yes No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY

SPI-611 #025 Concomitant Medications	# 098
Site No. Randomization No. Patient Initials	CM Page: $\boxed{1\ 0}$
CONCOMITANT MEDICATIONS	IVIAIN A II Last CIVI Fage.
List all medications taken at Week 0 and through Visit 4 (Month Serious Adverse Events throughout the study.	6). List medications taken for GU Adverse Events and
1. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? ☐ Yes ☐ No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY
2. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? ☐ Yes ☐ No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY
3. Name of Drug:	
Total Daily Dose: Units:	Start Date
Was medication taken for AE? ☐ Yes ☐ No	DD MMM YYYY
If YES, primary AE Page #: AE #:	Stop Date Continuing
If NO, record indication:	DD MMM YYYY

FORMS BEHIND EXTRA FORMS TAB

- Medical History (Additional)Physical Examination (Additional)
- Transurethral Resection
- Pathology
- Death Report

SPI-6	11 #025 Medical	History #004		
Site No.	Randomization No. Patient In	nitials		SCREENING
			DF C	Code: 0 1
			MH Pa	ge #:
MEDIC	AL HISTORY (Addition	al)	Mark "X" if Last	MH Page:
	cord any previous illnesses, surger imate date of onset (month and ye		the space provided below. Plea	ase provide
Body	mate date of oriest (mertal disa ye	ar). Abnomal		
System Code	Body System	Albri	If ABNORMAL, Specif	y
		П		
		_ 🗆		
		. ⊔		
		. 🗆		
		П		
		_ 🗆		
		. ⊔		
		_ 🗆		
	System Codes: 01 = Eyes 02 = Ears, Nose, Throat 03 = Respiratory 04 = Cardiovascular	05 = Gastrointestinal 06 = Musculoskeletal 07 = Skin	08 = CNS/Psychiatric 09 = Endocrine 93 = Other	

SPI-611 #	#025 Ph	ysical Exam #007		
Site No.	Randomization No. Pati	ent Initials	DF (Code:
PHYSICA	L EXAMINATION	(Additional)	PE Pa	ge #:
Exam Date:	DD MMM	YYYY	Mark "X" if Last	
Body System Code B	ody System	Athornal	If ABNORMAL, Speci	fy
* If Clinically	Significant (change from	m Baseline), documen	t relevant event on the Adverse Eve	ents CRF.
	Body System Codes: 01 = Skin 02 = Ears, Nose, Throa 03 = Neck/Thyroid	05 = Heart t 06 = Abdomen 07 = Urogenital	08 = Lymph Nodes 09 = Nervous System 93 = Other	

V7 - 14SEP2009

04 = Lungs

SPI-611 #025 Transurethral Resection #010		
Site No. Randomization No. Patient Initials	DF Code:	
TRANSURETHRAL RESECTION		
Date of Surgery: DD MMM YYYY		
TUR Start Time: TUR End Time: (00:00-23:59) (00:00-23:59)		
Total Number of Lesions:		
Size Lesion # Location Code <i>(Largest Diameter)</i>		
1 cm		
2 cm		
3		

Location Codes:

4.

A = Anterior Wall

D = Dome L = Left Wall N = Neck of Bladder P = Posterior Wall R = Right Wall T = Trigone

SPI-611 #025 Pathology #011	
Site No. Randomization No. Patient Initials	
	DF Code:
PATHOLOGY	
Report Date: DD MMM YYYY	
Pathology Report Source: Central Lab (Bostwick) (Mark One) Local Lab	
Highest pT Stage ^A :	
Highest Histologic Grade ^B :	
Will patient receive additional intravesical therapy (e.g. BCG, Mitomy	cin) for bladder cancer based on this report?
Yes (Report therapy on Concomitant Medication CRF)	
☐ No	

A - pT Stage Codes: **B - Histologic Grade Codes:**

1 = Ta 3 = T21 = G1

4 = Low Grade - WHO/ISUP 2 = T14 = Cis2 = G2

5 = High Grade - WHO/ISUP

SPI-611 #025 Death Report #101
Site No. Randomization No. Patient Initials
DEATH REPORT
Date of Death: DD MMM YYYY
Primary Cause of Death:

SAE Report required if death occurs within 28 days of last dose of study drug.

INTERIM VISIT

- Vital Signs
 Physical Examination (Brief)
 Urine Dipstick
 Cystoscopy
 Transurethral Resection

- Pathology

SPI-611 #025 Vital Signs #006	
Site No. Randomization No. Patient Initials	IM VISIT
DF Code:	9 9
Visit Date: Interim Visit #:	
VITAL SIGNS	
Exam Date: DD MMM YYYY	
Blood Pressure: / mmHg Systolic Diastolic	
Pulse: beats/minute (bpm)	
Temperature: °C	

SPI-611	#025 P	hysical Exam #007		
Site No.	Randomization No. Pa	tient Initials	IN	TERIM VISIT
			DF Co	ode: 99
			Interim Vis	it #:
PHYSIC	AL EXAMINATION	l (Brief)	PE Page	e #:
Exam Date:	DD MMM	YYYY	Mark "X" if Last I	PE Page:
Body System Code	Body System LUNGS	Hornal Abrornal Done	If ABNORMAL, Specify	<i>'</i>
0 5	HEART			
06	ABDOMEN			
		. 🗆 .		
		. 🗆 .		
		. 🗆 .		
		. 🗆 .		
		. 🗆 .		
		. 🗆 .		
		. 🗆 .		
* If Clinical	ly Significant (change fro	om Baseline), document	relevant event on the Adverse Even	ts CRF.
	Body System Codes: 01 = Skin 02 = Ears, Nose, Thro 03 = Neck/Thyroid 04 = Lungs	05 = Heart	08 = Lymph Nodes 09 = Nervous System 93 = Other	

SPI-611 #025	Jrine Dipstick / Urine Cytology #009	
Site No. Randomization No. Pa	atient Initials IN	TERIM VISIT
	DF Co	de: 99
URINE DIPSTICK	Interim Visit k "X" if Not Done	#:
Collection Date: DD MMM		***************************************
Test Result		if Abnormal and lly Significant*
Specific Gravity		
рН		
Protein Negative	Trace 1+ 2+ 3+ 4+	
	Non-Hemolyzed Hemolyzed	
Blood Negative	Trace Moderate Trace 1+ 2+ 3+	
Glucose Negative] 100	
Leukocyte Negative] Trace	
Nitrite Negative	Positive	
If patient is leukocyte esterase or nitrit analysis. Otherwise, do not send urin	te positive by urine dipstick, send urine sample to central lab for me sample to central lab.	icroscopic
Microscopic Exam Mark "X" i	f Not Done	
Collection Date: DD MMM	YYYY	
URINE CYTOLOGY N	Mark "X" if Not Done	
Collection Date:	YYYY	

^{*} If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.

SPI-611 #025	Cystoscopy #013			
Site No. Randomization No.	Patient Initials		INTER	IM VISIT
			DF Code:	99
			Interim Visit #:	
CYSTOSCOPY				
Exam Date: DD MMM	YYYY			
Is the site of initial TUR re-epithelial	ized? Yes	No		
Were any tumors seen? Yes	s No			
If YES, were any biopsies perfo	rmed?			
		Location:	,	
Yes If YES, enter loc	ation from code list below			
No If NO, explain:				
Were any other abnormalities seen?	?			
Yes If YES, explain:				
☐ No				

Location Codes:

 $\begin{array}{ll} \mbox{A = Anterior Wall} & \mbox{N = Neck of Bladder} & \mbox{R = Right Wall} \\ \mbox{D = Dome} & \mbox{P = Posterior Wall} & \mbox{T = Trigone} \\ \end{array}$

L = Left Wall

SPI-611 #025	Transure	thral Resection	#010			
Site No. Randomization	n No. Patient Ini	itials			INTER	IM VISIT
					DF Code:	9 9
TRANSURETHRAL	RESECTIO	N			Interim Visit #:	
Date of Surgery:	MMM	УУУУ				
TUR Start Time:	(00:00-23:59)	TUR En	d Time:	(00:00-23:59)		
Total Number of Lesions:						
	Lesion # Lo	ocation Code	Siz (Largest L			
	1.			_ cm		
	2.			_ cm		
	3.			_ cm		

Location Codes:

4.

A = Anterior Wall

D = Dome L = Left Wall N = Neck of Bladder

P = Posterior Wall

R = Right Wall T = Trigone

SPI-611 #025	Pathology #011		
Site No. Randomization	on No. Patient Initials	INTERI	M VISIT
		DF Code:	99
		Interim Visit #:	
PATHOLOGY			
Report Date:	MMM YYYY		
Pathology Report Source: (Mark One)	Central Lab (Bostwick) Local Lab		
Highest pT	Stage ^A :		
Highest His	stologic Grade ^B :		
Yes (Report therapy	al intravesical therapy (e.g. BCG, Mitom	nycin) for bladder cancer based on this rep	oort?
□ No			

A - pT Stage Codes:

B - Histologic Grade Codes:

1 = Ta 3 = T2 1 = G1 3 = G

2 = T1 4 = Cis 2 = G2 4 = Low Grade - WHO/ISUP

5 = High Grade - WHO/ISUP

SITE SPECIFIC ASSESSMENT PACKET

Wrap for Subjects at Selected Sites Only

- Screening Visit (4 Pages) Insert behind page 9
- Visit 6 Month 12 (4 Pages) Insert behind page 36
- Visit 10 Month 24 (4 Pages) Insert behind page 52

SPI-611 #025 Blac	dder Capacity / Postvoid Residual Measurement #014		
Site No. Randomization No. Patie	ent Initials	SCR	EENING
		DF Code:	0 1
BLADDER CAPACITY			
Date of Measurement:	MMM YYYY		
Voided Volume: mL			
POSTVOID RESIDUAL MEA	ASUREMENT (ULTRASOUND)		
1 GOT VOID REGIDORE MEA	ROUNEMENT (GETRAGOGNE)		
Date of Ultrasound:	MMM YYYY		
Postvoid Residual Volume:	mL		

SI	PI-611 #025	Pat	tient Voiding Diary	#015			
Site	No. Randomizatio	n No. Pati	ent Initials			S DF Cod	CREENING
						DP Cou	e: $\boxed{0}$ $\boxed{1}$
PAT	IENT VOIDING	DIARY -	DAY 1				DAI. 1
Date:	DD MMM	YY	YY				
	TIME (12 Hour Clock)		VOLUME (oz)		TIME (12 Hour Clock)		VOLUME (oz)
1.		☐ AM ☐ PM		11.		☐ AM ☐ PM	
2.		☐ AM ☐ PM		12.		☐ AM ☐ PM	
3.		☐ AM		13.		☐ AM	
4.	<u></u> ::	☐ AM		14.		☐ AM ☐ PM	
5.	<u></u> ::::::::::::::::::::::::::::::::::::	☐ AM		15.		☐ AM	
6.	<u></u> :	☐ AM		16.		☐ AM	
7.	<u></u> ::	☐ AM		17.		☐ AM	
8.		☐ AM		18.		☐ AM	
9.		☐ AM ☐ PM		19.		☐ AM ☐ PM	
10.	<u></u> ::	☐ AM		20.		☐ AM	

SI	PI-611 #025	Pat	ient Voiding Diary	#015	ı		
Site	No. Randomizatio	n No. Patio	ent Initials			S(DF Code	CREENING 9: 0 1
						Di Cou	
PAT	IENT VOIDING	DIARY -	DAY 2				DAY: 2
Date:	DD MMM	YY	YY				
	TIME (12 Hour Clock)		VOLUME (oz)		TIME (12 Hour Clock)		VOLUME (oz)
1.		☐ AM ☐ PM		11.		☐ AM ☐ PM	
2.		☐ AM ☐ PM		12.		☐ AM ☐ PM	
3.		☐ AM		13.		☐ AM	
4.		☐ AM		14.		☐ AM	
5.	<u></u> ::	☐ AM		15.	<u></u> ::	☐ AM	
6.	<u></u> ::	☐ AM		16.	<u></u> ::	☐ AM	
7.	<u></u> ::	☐ AM		17.	-:	☐ AM	
8.	<u></u> ::	☐ AM		18.	-:	☐ AM	
9.	:	☐ AM ☐ PM		19.		☐ AM	
10.	<u></u> :	☐ AM		20.	<u></u> ::	☐ AM	

SI	PI-611 #025	Pat	ient Voiding Diary	#015	ı		
Site	No. Randomizatio	n No. Patio	ent Initials			S(DF Cod	CREENING e: 01
						DI 000	
PAT	IENT VOIDING	DIARY -	DAY 3				DAY: 3
Date:	DD MMM	YY	YY				
	TIME (12 Hour Clock)		VOLUME (oz)		TIME (12 Hour Clock)		VOLUME (oz)
1.		☐ AM ☐ PM		11.		☐ AM ☐ PM	
2.		☐ AM ☐ PM		12.		☐ AM ☐ PM	
3.		☐ AM		13.		☐ AM	
4.	<u></u> :	☐ AM ☐ PM		14.		☐ AM ☐ PM	
5.	<u></u> :	☐ AM		15.	<u></u> ::	☐ AM	
6.	<u></u> ::	☐ AM		16.	-:	☐ AM	
7.	<u></u> ::	☐ AM		17.	-:	☐ AM	
8.	<u></u> ::	☐ AM		18.	-:	☐ AM	
9.	:	☐ AM ☐ PM		19.		☐ AM ☐ PM	
10.	<u></u> :	☐ AM		20.	<u></u> ::	☐ AM	

SPI-611 #025 Bladder Capacity / Postvoid Residual Measurement #01	4	
Site No. Randomization No. Patient Initials	VISIT 6: M	ONTH 12
	DF Code:	0 7
BLADDER CAPACITY		
Date of Measurement: DD MMM YYYY		
Voided Volume: mL		
POSTVOID RESIDUAL MEASUREMENT (ULTRASOUND)		
Date of Ultrasound: DD MMM YYYY		
Postvoid Residual Volume: mL		

S	PI-611 #025	Pat	ient Voiding Diary	#015			
Site	No. Randomizatio	n No. Pati	ent Initials			VISIT 6:	MONTH 12 le: 0 7
PAT	IENT VOIDING	DIARY -	DAY 1				DAY: 1
Date:	DD MMM	YY	YY				
	TIME (12 Hour Clock)		VOLUME (oz)		TIME (12 Hour Clock)		VOLUME (oz)
1.		☐ AM ☐ PM		11.		☐ AM ☐ PM	
2.		☐ AM		12.		☐ AM ☐ PM	
3.	<u>:</u>	☐ AM		13.	-:	☐ AM	
4.		☐ AM		14.		☐ AM ☐ PM	
5.	<u> </u>	☐ AM		15.	<u></u> ::	☐ AM	
6.	<u></u> ::	☐ AM		16.	-:	☐ AM	
7.	<u>:</u> :	☐ AM		17.	-:	☐ AM	
8.	<u></u> ::	☐ AM		18.	-:	☐ AM	
9.	<u></u> :	☐ AM		19.	:	☐ AM ☐ PM	
10.	<u></u> ::::::::::::::::::::::::::::::::::::	☐ AM		20.		☐ AM	

S	PI-611 #025	Pat	ient Voiding Diary	#015			
Site	No. Randomizatio	on No. Patio	ent Initials			VISIT 6:	month 12
PAT	IENT VOIDING	DIARY -	DAY 2				DAY: 2
Date:	DD MMM	YY	YY				
	TIME (12 Hour Clock)		VOLUME (oz)		TIME (12 Hour Clock)		VOLUME (oz)
1.		☐ AM ☐ PM		11.		☐ AM ☐ PM	
2.		☐ AM ☐ PM		12.		☐ AM ☐ PM	
3.	<u></u> ::	☐ AM		13.	<u></u> ::	☐ AM	
4.		☐ AM ☐ PM		14.		☐ AM ☐ PM	
5.	-:	☐ AM ☐ PM		15.		☐ AM ☐ PM	
6.	<u></u> ::	☐ AM		16.	<u></u> ::	☐ AM	
7.	<u></u> ::	☐ AM		17.	<u></u> ::	☐ AM	
8.	<u></u> ::	☐ AM		18.	<u></u> ::	☐ AM	
9.	:	☐ AM ☐ PM		19.		☐ AM ☐ PM	
10.	<u></u> :::	☐ AM		20.	<u></u> :	☐ AM	

S	PI-611 #025	Pat	ient Voiding Diary	#015			
Site	No. Randomizatio	n No. Patio	ent Initials			VISIT 6:	MONTH 12 e: 0 7
PAT	IENT VOIDING	DIARY -	DAY 3				DAY: 3
Date:	DD MMM	YY	YY				
	TIME (12 Hour Clock)		VOLUME (oz)		TIME (12 Hour Clock)		VOLUME (oz)
1.		☐ AM ☐ PM		11.		☐ AM ☐ PM	
2.	<u></u> ::	☐ AM ☐ PM		12.		☐ AM ☐ PM	
3.	<u></u> ::	☐ AM		13.	<u></u> :	☐ AM	
4.	<u></u> ::	☐ AM		14.		☐ AM ☐ PM	
5.	<u></u> :	☐ AM		15.	<u></u> :	☐ AM	
6.	<u></u> ::	☐ AM		16.	-:	☐ AM	
7.	<u></u> ::	☐ AM		17.	-:	☐ AM	
8.	<u></u> ::	☐ AM		18.	-:	☐ AM	
9.	<u></u> ::	☐ AM		19.	:	☐ AM	
10.	<u></u> :	☐ AM		20.		☐ AM	

SPI-611 #025	Bladder Capacity / Postvoid Residual Mea	asurement #014
Site No. Randomization No.	Patient Initials	VISIT 10: MONTH 24
		DF Code: 1 1
BLADDER CAPACITY		
Date of Measurement:	MMM YYYY	
Voided Volume: ml	L	
BOSTVOID BESIDIIAL I	MEACUDEMENT (III TDACOU	NID)
POSTVOID RESIDUAL II	MEASUREMENT (ULTRASOU	ND)
Date of Ultrasound:	MMM YYYY	
Postvoid Residual Volume:	mL	

SI	PI-611 #025	Pat	tient Voiding Diary	#015			
Site	No. Randomizatio	n No. Pati	ent Initials			VISIT 10:	MONTH 24
						DF Cod	e: 111
PAT	IENT VOIDING	DIARY -	DAY 1				DAY: 1
Date:	DD MMM	YY	YY				
	TIME (12 Hour Clock)		VOLUME (oz)		TIME (12 Hour Clock)		VOLUME (oz)
1.		☐ AM ☐ PM		11.		☐ AM ☐ PM	
2.		☐ AM ☐ PM		12.		☐ AM ☐ PM	
3.		☐ AM		13.	<u>:</u> :	☐ AM	
4.	<u></u> ::	☐ AM		14.	<u>:</u> :	☐ AM ☐ PM	
5.	<u></u> ::::::::::::::::::::::::::::::::::::	☐ AM		15.	<u> </u>	☐ AM	
6.	<u></u> :	☐ AM		16.	<u> </u>	☐ AM	
7.	<u></u> ::	☐ AM		17.	-:	☐ AM	
8.		☐ AM		18.	<u>:</u> :	☐ AM	
9.		☐ AM ☐ PM		19.	-:	☐ AM ☐ PM	
10.	<u></u> ::	☐ AM		20.	<u> </u>	☐ AM	

S	PI-611 #025	Pat	ient Voiding Diary	#015			
Site	No. Randomizatio	n No. Pati	ent Initials			VISIT 10:	MONTH 24
						DF Cod	e: 1 1
PAT	IENT VOIDING	DIARY -	DAY 2				DAY: 2
Date:	DD MMM	YY	YY				
	TIME (12 Hour Clock)		VOLUME (oz)		TIME (12 Hour Clock)		VOLUME (oz)
1.		☐ AM ☐ PM		11.		☐ AM ☐ PM	
2.		☐ AM ☐ PM		12.		☐ AM ☐ PM	
3.		☐ AM		13.	<u></u> :::	☐ AM	
4.		☐ AM ☐ PM		14.	-:	☐ AM ☐ PM	
5.	<u></u> :	☐ AM		15.	<u> </u>	☐ AM ☐ PM	
6.	<u></u> ::	☐ AM		16.	<u> </u>	☐ AM ☐ PM	
7.		☐ AM ☐ PM		17.	-:	☐ AM	
8.		☐ AM ☐ PM		18.	-:	☐ AM	
9.		☐ AM		19.	:	☐ AM	
10.	<u></u> :	☐ AM		20.	<u> </u>	☐ AM	

S	PI-611 #025	Pat	lent Voiding Diary	#015			
Site	No. Randomizatio	n No. Patie	ent Initials			VISIT 10:	MONTH 24
						DF Cod	e: 1 1
PAT	IENT VOIDING	DIARY -	DAY 3				DAY: 3
Date:	DD MMM	YY	YY				
	TIME (12 Hour Clock)		VOLUME (oz)		TIME (12 Hour Clock)		VOLUME (oz)
1.		☐ AM ☐ PM		11.		☐ AM ☐ PM	
2.		☐ AM ☐ PM		12.		☐ AM ☐ PM	
3.		☐ AM		13.	<u></u> :::	☐ AM	
4.		☐ AM ☐ PM		14.	-:	☐ AM ☐ PM	
5.	<u></u> :	☐ AM		15.	<u> </u>	☐ AM ☐ PM	
6.	<u></u> ::	☐ AM		16.	<u> </u>	☐ AM ☐ PM	
7.		☐ AM ☐ PM		17.	-:	☐ AM	
8.		☐ AM		18.	-:	☐ AM	
9.		☐ AM		19.	:	☐ AM	
10.	<u></u> :	☐ AM		20.	<u> </u>	☐ AM	

SHRINK WRAP PACKETS TO SPONSOR

Site Screening Log Documentation of Protocol Violations Adverse Events Concomitant Medications

SPI-611 #025	Site Screening Log #254
Site No. SITE SCREE	Page: ☐☐ Mark "X" if Last Page: ☐
	Completion Instructions to correctly complete this form.
Please fax to Synt	eract weekly by 4:00 pm (PST) on Friday.
Patient Initials: Date Consented:	Screening No.: Randomization No.: DD MMM YYYY
Screen Fail?	Yes, Reason for Screen Failure:* If "04" or "05", specify criterion #: No
Patient Initials: Date Consented: Screen Fail?	Screening No.: Randomization No.:
- Corcon run.	No
Patient Initials: Date Consented:	Screening No.: Randomization No.: DD MMM YYYY
Screen Fail?	Yes, Reason for Screen Failure:* If "04" or "05", specify criterion #: No
	*Reason for Screen Failure Codes: 01 = Withdrew Consent or HIPAA

SPI-6	11 #025	Document	tation of Protocol Violations #251				
Site No.	Random	nization No. Patient Initi	ials				
				Pa	nge:		
				Mark "X" if La	ast Page:		
			COL VIOLATIONS				
To be com	pleted by the	e Spectrum CRA only.					
1. Inclusi	on/Exclusio	on Criteria violation with	hout exception granted by medica	al director.			
(Note: CR	A to ensure t	that appropriate boxes or	n CRF are checked).				
Violation Code ^A	Criteria #		Specify	IRB Repor	ted? CRA Initials		
			Эреспу	Yes 1	No Initials		
				□ [
					<u> </u>		
					_		
				Ы [
				[
2. Other	Violations (F	Please include dates)					
Violation Start Date			IRB Repor	ted? CRA			
Code ^A		(DD/MMM/YYYY)	Specify		Initials No		
				[<u> </u>		
							
				[<u> </u>		
				[
A - Viols	ation Codes:						
01 = Inf	ormed Cons		06 = SAE Reporting	11 = Noncomplianc			
		ria (Specify criteria #) eria (Specify criteria #)	07 = Regulatory 08 = Drug Storage/Preparation	missed measu 93 = Other, specify	res)		
04 = Cc	ncomitant M		09 = Drug Administration	223., opeany			
05 = Laboratory 10 = Visit Schedule							

	SPI-611 #025	Adverse Events #097						
	te No. Randomization No.	o. Patient Initials		AE Page #: Mark "X" if Last AE Page:				
	Collect all Adverse Events through Visit 4 (6 Months). Collect genitourinary Adverse Events for the patient's entire participation in the study.							
1.	Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY				
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)				
2.	Adverse Event Term: Start Date: DD	MMM YYYY	Stop Date:	DD MMM YYYY				
	Serious? Yes (Notify Sponsor) No	Toxicity Grade 1-Mild 2-Moderate 3-Severe 4-Life threatening 5-Fatal	Relationship to Study Drug Unrelated Unlikely Possible Probable Definite	Outcome Persisted at end of study Resolved with sequelae Resolved without sequelae Death (If caused by this AE)				

SPI-611 #025 Concomitant Medications #	1 098
Site No. Randomization No. Patient Initials CONCOMITANT MEDICATIONS	CM Page: Mark "X" if Last CM Page:
List all medications taken at Week 0 and through Visit 4 (Month 6 Serious Adverse Events throughout the study. 1. Name of Drug: Total Daily Dose: Units: Was medication taken for AE? Yes No	Start Date
If YES, primary AE Page #: AE #: If NO, record indication: 2. Name of Drug:	Stop Date Continuing DD MMM YYYY Stop Date Continuing
Total Daily Dose: Was medication taken for AE? Yes No If YES, primary AE Page #: AE #: If NO, record indication:	Start Date DD MMM YYYY Stop Date Continuing DD MMM YYYY
Total Daily Dose: Was medication taken for AE? Yes No If YES, primary AE Page #: AE #:	Start Date DD MMM YYYY Stop Date Continuing DD MMM YYYY

INTERNAL FORMS (Printer does not print)

DCF

SPI-611 #025 Data Clarification For	m #250			
Site No. Randomization No. Patient Initials		Qu	ery Page i	#:
DATA CLARIFICATION FORM				
CRF Page(s):				
Visit:				
Clarification/Change Required:	Resolution:			
By signing in the space provided below, the investigator ac noted above.	cknowledges his/her ap	proval of	the clarific	cations/changes
	Date:			
Principal Investigator Signature		DD	MMM	YYYY

SPI-611 #025 Original CRF Retrieval	Approval Form #25	5			
Site No. Randomization No. Patient Initials					
ORIGINAL CRF RETRIEVAL APPROVAL	. FORM				
All Documentation of Protocol Violations CRFs hav	e been faxed into Da	ıtaFax.			
2. All visits for this subject have been fully monitored.					
I confirm that all required original Case Report Forms for this subject are ready to be sent to Synteract:					
0004	Date:				
CRA		DD	MMM	YYYY	