WORTHAM LABORATORIES, INC.

SeraSeal
A Primary Hemostatic Agent

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with friends, relatives, and your physician if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Purpose of this Study

Hemorrhages (bleeds) require an immediate response to stop the bleeding. There are two means to treat hemorrhages: pressure and cauterization. Direct pressure or the use of a tourniquet is commonly used, while chemical, electrical or laser cauterization, gives a more immediate response to bleeds. Each method has its own limits and effectiveness.

A biological, called SeraSeal, developed by Wortham Laboratories, Inc. is designed to stop bleeding, even in the face of challenging situations, such as anticoagulant therapy, and factor deficiencies. Unlike current methods to treat hemorrhages, SeraSeal requires no pressure, and does not burn or cause tissue damage.

This clinical research study will evaluate the safety and efficacy of SeraSeal, in the treatment of hemorrhages, for both surgical and non-surgical procedures.

Enrollment

Subjects selected for this study are those who are having a hemorrhagic episode, or those who will incur bleeding as a result of an incision, debreedment insertion or any other method that may induce bleeding.

This study is open to all patients experiencing blood loss, however, those subjects diagnosed with Lupus or those who are allergic to bovine products, should consult with their physician.

To test the safety and efficacy of SeraSeal, a total of 120 patients will be tested.

Participation

This study is intended to be a one-time treatment. Blood is drawn before the procedure, and again 4-8 hours after treatment. Each patient undergoing surgery will have a repeat blood test 12-24 hours after the operation.

6.2 Demographic Characteristics

Table 8 summarizes the demographic characteristics of all patients that were entered in the study. There were more female than male patients and all of them were Hispanic in all treatment groups. In the SeraSeal syringe treatment group more male patients were between the ages of 60-69 years, while there were more 40-49 year old female patients. In the spray delivery treated group, more 20-29 year old male and 40-49 year old female patients were in these age ranges. Although those were twice as many spray delivery system cases in this study, the demographic characteristics were generally balanced among the two treatment groups.

Table 8 Demographic Characteristics

Demographic Characteristic	Treatment Group: SeraSeal Syringe (n=36)		SeraSeal Spray (n=84)	
Sex	**M**	**F**	**M**	**F**
	15 (41.7%)	21 (58.3%)	33 (39.3%)	51 (60.7%)
Age (years)				
18-19	0 (0.00%)	1 (2.8%)	1 (1.2%)	1 (1.2%)
20-29	1 (2.8%)	0 (0.00%)	10 (11.9%)	1 (1.2%)
30-39	3 (8.3%)	4 (11.1%)	5 (5.9%)	10 (11.9%)
40-49	2 (5.6%)	6 (16.6%)	4 (4.8%)	13 (15.4%)
50-59	2 (5.6%)	4 (11.1%)	7 (8.3%)	9 (10.7%)
60-69	4 (11.1%)	4 (11.1%)	2 (2.4%)	12 (14.3%)
70-79	3 (8.3%)	1 (2.8%)	3 (3.6%)	3 (3.6%)
80-86	0 (0.00%)	1 (2.8%)	1 (1.2%)	2 (2.4%)
Weight (lb)	(n=15)	(n=21)	(n=33)	(n=51)
mean ± SD	163.6 ± 11.1	143.9 ± 9.5	159.6 ± 6.3	142.0 ± 10.5
Range	148-182	125-158	147-179	118-165
Height (in)	(n=15)	(n=21)	(n=33)	(n=51)
mean ± SD	67.5 ± 3.0	64.1 ± 1.9	68.1 ± 1.7	63.8 ± 1.7
Range	67-72	62-69	65-71	60-70

Ref. Demographic Data Listing, appendix 12.2.3 and Efficacy Response Data Listing, appendix 12.2.4.

7. Efficacy Evaluation

7.1 Data Sets Analyzed

7.1.1 Number and Distribution of Patients

A total of 120 patients participated in this study at 3 centers; all of the centers were in Havana, Cuba. Of the 120 patients, a total of 117 completed the surgical procedure without the use of a surgical modality to control bleeding; 36 (100%) in the SeraSeal syringe group,

81 (96.4%) in the SeraSeal spray group. The number of patients from each study center and the number who completed treatment is shown by treatment group in Table 9.

Table 9 Number in Each Enrolled (E) Group and Who Completed *(C) Surgical Treatment at Each Center

		Treatment Group			
		SeraSeal Syringe		SeraSeal Spray	
Center No.	Site	E	C	E	C
1	Joaquin Albarran Hospital	26	26	63	63
2	Salvador Allende Hospital	4	4	6	6
3	National Institute Cardiovascular	6	6	15	12

* Completed treatment is defined as no other surgical modality to control bleeding

7.1.2 Withdraw Reasons

There were 3 (2.5%) therapeutic breaks to complete the entire surgical procedure without the use of standard surgical methods to control bleeding. The number of cross-over patients and the reasons for withdrawal are shown in Table 10.

Table 10 Therapeutic Break From SeraSeal to Standard Surgical Modality

Case Number	Surgical Procedure	SeraSeal Treatment Group	Reason for Therapeutic Break
CV02	Disarticulation – 2nd Artery	Spray	Arterial bleed larger than the design of the spray applicator
CV08	Disarticulation – 2nd Artery	Spray	Collective hemostatic time greater than the prescribed 5 minutes
CV14	Disarticulation – 2nd Artery	Spray	Arterial bleed larger than the design of the spray applicator

7.2 Demographic and Other Baseline Characteristics

Table 11 summarizes baseline characteristics regarding the two SeraSeal treatment groups. Most of the patients (79%) were in the spray treatment group, but there was no significant differences between the vial and spray groups (P=0.3074) or gender (P=0.1497). The overall hematological profile for both treatment groups was normal. Fifty eight percent (58%) of the SeraSeal syringe treatment group were on warfarin, while only 6% of the patients in the spray treatment group were on warfarin. Proportionately, there was a balance in the number of associated illnesses between the two treatment groups. The surgical procedure and the intended targeted organ reflected the type of delivery system to be used. Hemorrhages from larger blood vessels, those patients were placed in the syringe treatment group, while the majority of bleeds to be encountered were of capillary to small blood vessels in size, those patients were placed in the spray treatment group.

Table 11 Baseline Characteristics

Baseline Characteristics	Treatment Group SeraSeal Syringe (N=36)		SeraSeal Spray (N=34)	
	15 (41.7%)	21 (58.3%)	33 (39.3%)	51 (60.3%)
Pre-Op Mean (SD)	**M**	**F**	**M**	**F**
HBG (g/dl)	13.0±1.6	12.5±1.0	13.3±1.6	12.1±1.8
HCT (%)	37.7±4.4	36.7±2.2	42.0±5.2	39.2±2.7
PT (sec)	13.4±1.0	13.8±2.3	11.9±0.3	11.9±0.3
PTT (sec)	28.7±3.6	26.6±2.4	30.1±1.9	30.4±2.8
Anticoagulant Therapy (warfarin) Number	11 (73.3%)	10 (47.6%)	2 (5.6%)	3 (5.9%)
Dose (mg) Mean (SD)	4.8±1.3	11.4±16.4	5.0±0	3.3±1.4
Associated Illness				
Arterial Hypertension	1 (2.8%)		0 (0.00%)	
Diabetes Mellitas	5 (13.9%)		10 (11.9%)	
Hemophelia	0 (0.00%)		1 (1.2%)	
Surgical Specialty Mean (SD)				
Angiology	16 (44.4%)		12 (14.2%)	
General Surgery	9 (25.0%)		15 (17.9%)	
Proctology	7 (19.5%)		25 (29.8%)	
Urology	4 (11.1%)		0 (0.00%)	
ENT	0 (0.00%)		20 (23.8%)	
Orthopedic	0 (0.00%)		3 (3.5%)	
Facial Surgery	0 (0.00%)		1 (1.2%)	
Targeted Organ				
breast	4 (11.1%)		2 (2.4%)	
vascular	6 (16.7%)		10 (11.9%)	
bone	5 (13.9%)		7 (8.3%)	
bowel	0 (0.00%)		5 (6.0%)	
anus	7 (19.4%)		21 (25.0%)	
prostate	4 (11.1%)		6 (7.1%)	
parotid	0 (0.00%)		1 (1.2%)	
thyroid	3 (8.3%)		1 (1.2%)	
kidney	0 (0.00%)		1 (1.2%)	
tonsil	0 (0.00%)		19 (22.6%)	
skin-muscle	7 (19.4%)		6 (7.1%)	
uterus	0 (0.00%)		4 (4.8%)	
bladder	0 (0.00%)		1 (1.2%)	

Ref. Individual Patient Data Listing, appendix 12.4.

7.3 Efficacy Results and Tabulation of Individual Patient Data

7.3.1 Analysis of Efficacy

The primary efficacy measurement defined by the protocol stated that all bleeding throughout the entire surgical procedure (skin-skin) had to be controlled solely by a single SeraSeal delivery system and the time to hemostasis for all of the treated wounds during the surgical procedure, collectively, to be less than 5 minutes in 90% of the total surgical cases.

All of the SeraSeal syringe treatment group had a total hemostasis time of one minute, while the SeraSeal spray treatment group had a hemostasis range of 1-7 minutes with a mean time of 1.48 minutes, Table 12. To control the bleeding a dosage range of 1500-6000 IU (mean 4650 IU) and 1500-15,000 IU (mean 4412 IU) were applied in the SeraSeal syringe and spray treatment groups, respectively. Due to the nebulizing effect of the spray, twice the dosage was applied to the heavier hemorrhagic events that occurred in the spray treatment group. Comparing the time to hemostasis for SeraSeal to that of cauterization, this difference was statistically significant (P=0.0001).

Twenty six subjects (21.7%) were on warfarin. Twenty one were placed in the vial group and 5 in the spray delivery group. The mean warfarin dosage was 5.0 mg (±1.37) and 4.0 mg (±1.37), respectively. There was no significant difference (P=0.2951) between the two groups. Comparing normal patients to warfarin patients, the mean SeraSeal dosage needed to achieve hemostasis was 3,802 IU and 3,404 IU, respectively, with a mean 1.39 and 1.15 minute time to hemostasis. SeraSeal was effective in both normal and anticoagulant patients, with no significant difference between the two groups (P=0.2666).

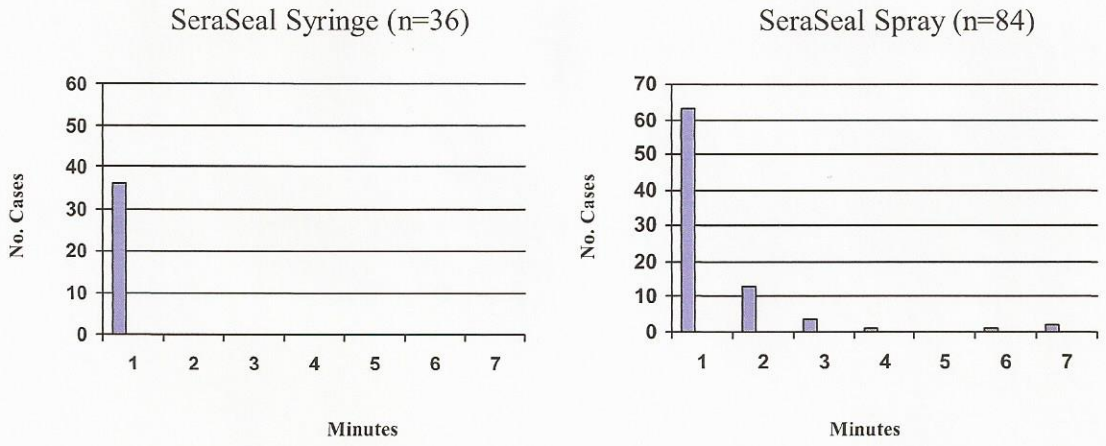
There were three therapeutic breaks of SeraSeal to cauterization, while using the spray delivery system. In two cases, the abandonment was due to the surgeon accidentally creating an arterial bleed larger than the design of the spray applicator (1.7%). The third case was due to not achieving hemostasis within the prescribed 5 minutes (0.8%). The overall performance of SeraSeal to control all forms of bleeding with one type of delivery system was 97.5%, Graph 1.

Table 12 Efficacy of Both SeraSeal Treatment Groups

Baseline Characteristics	Treatment Group SeraSeal Syringe (N=36)		SeraSeal Spray (N=84)	
Time to Hemostasis				
mean	1.00		1.48	
SD (±)	0		1.18	
range	1		1-7	
Dosage (IU)				
mean	2650		4412	
SD (±)	1179		3281	
range	1500-6000		1500-15,000	
Number of SeraSeal Applications				
No. Applications/No. Cases				
1	3	(8.3)	28	(33.3)
2	5	(13.9)	19	(22.6)
3	7	(19.4)	8	(9.5)
4	12	(33.3)	13	(15.5)
5	5	(13.9)	8	(9.5)
6	4	(11.1)	3	(3.6)
7	-	-	2	(2.4)
8	-	-	3	(3.6)
Attempts/Bleeds	1 (n=36)		1 (n=81) 3 (n=3)	
Therapeutic Break	0		3	

Ref. Individual Patient Data Listing, appendix 12.4.

Graph 1 Efficacy – Time to Hemostasis



7.3.2 Statistical/Analytical Issues

Using the collective times to hemostasis in each surgical case as a measure of efficacy, we examined the number of patients solely treated with SeraSeal to the number of patients who crossed-over to a surgical modality to arrest the hemorrhages. To demonstrate efficacy, this study required ninety-five percent (95%) of the SeraSeal treated patients to have a total hemostasis time of under 5 minutes, in surgical cases known to take more than 6 minutes through standard primary surgical methods to control bleeding.

In the SeraSeal syringe treatment group (n=36) no cross-over had occurred with a mean time to hemostasis of 1.00 (± 0) minutes. Three therapeutic breaks had occurred in the SeraSeal spray treatment group (n=84), producing a mean 1.48 (± 1.12) minutes, with the therapeutic breaks included. This resulted in a 96.4% success rate for the SeraSeal spray delivery system. The two treatment groups together had a high statistical significance ($p< 0.001$), with a mean hemostatic time of 1.34 (± 1.01) minutes and a 97.5% achievement rate of SeraSeal, to be used skin to skin.

7.3.3 Tabulation of Individual Response Data

Tabulation of Individual Response lists the target organs, the type of tissue where SeraSeal was applied, the total dosage exposure, collective time to hemostasis are listed in appendix 12.2.4, page 81.

7.3.4 Dosage, Activity Level, and Relationship to Response

The activity level for both SeraSeal delivery systems were 3,000 IU/ml. The mean dosage level in the SeraSeal syringe treatment group was 2650 IU (± 1179 IU), while the SeraSeal spray delivery system administered a mean of 4412 IU (± 3281 IU). The varience of drug dosage observed was due to the surgical procedure and the type of delivery system used for that particular surgical case. Typically, twice the amount of SeraSeal was applied in the spray treatment group, as a result of the nebulizing effect of the spray. The nebulizing effect created less IU/cm^2 than the syringe delivery system.

7.3.5 Efficacy Conclusion

There were three abandonment of SeraSeal cases, while using the spray delivery system for another hemostatic procedure. In two cases, the abandonment was due to the surgeon accidentally creating an arterial bleed larger that the design of the spray applicator 2/84 (1.7%). The third case was due to not achieving hemostasis within the prescribed 5 minutes 1/84 (0.8%). The overall performance of SeraSeal to control all forms of bleeding with one type of delivery system was 97.5% (117/120).

12.2.4 Individual Response List

Case No.	Targeted Organ	Dosage IU	Treated Tissue	Total Hemostasis (min)	Therapeutic Break (Y/N)
SA-01	uterus	12K	ep,d,sub,p,m,a,v	3	N
SA-02	uterus	9K	ep,d,sub,p,m,a,v	2	N
SA-03	mammary	6K	ep,d,sub,ad,p,m,a,v	1	N
SA-04	uterus	6K	ep,d,sub,p,m,a,v	3	N
SA-05	mammary	15K	ep,d,sub,ad,p,m,a,v	2	N
SA-06	uterus	9K	ep,d,sub,p,m,a,v	3	N
SA-07	mammary	2.1K	ep,d,sub,ad,p,m,a,v	1	N
SA-08	mammary	6K	ep,d,sub,ad,p,m,a,v	1	N
SA-09	mammary	1.5K	ep,d,sub,ad,p,m,a,v	1	N
SA-10	mammary	3k	ep,d,sub,ad,p,m,a,v	1	N
CV-01	vascular	6k	ep,d,sub,a	4	N
CV-02	vascular	9K	ep,d,sub,a	6	Y
CV-03	vascular	7.5K	ep,d,sub,a,v	3	N
CV-04	vascular	7.5K	ep,d,sub,a,v	2	N
CV-05	vascular	7.5K	ep,d,sub,a,v	2	N
CV-06	leg amputation	6K	ep,d,sub,m,a,v,b	1	N
CV-07	leg amputation	6K	ep,d,sub,m,a,v,b	1	N
CV-08	vascular	12K	ep,d,sub,a	7	Y
CV-09	close amputation	3K	ep,d,sub,m	1	N
CV-10	vascular	6K	ep,d,sub,a,v	2	N
CV-11	leg amputation	7.5K	ep,d,sub,m,a,v,b	1	N
CV-12	vascular	4.5K	ep,d,sub,a,v	2	N
CV-13	vascular	4.5K	ep,d,sub,a	1	N
CV-14	vascular	15K	ep,d,sub,a	7	Y
CV-15	leg amputation	6K	ep,d,sub,m,a,v,b	1	N
CV-16	vascular	4.2K	ep,d,sub,v	1	N
CV-17	vascular	3K	ep,d,sub,v	1	N
CV-18	vascular	3K	ep,d,sub,v	1	N
CV-19	vascular	3K	ep,d,sub,v	1	N
CV-20	vascular	3.9K	ep,d,sub,v	1	N
CV-21	vascular	3K	ep,d,sub,v	1	N
JA-01	bowel	7.5K	ep,d,sub,ad,m,p,me,a,v	1	N
JA-02	anus	1.5K	ep,d,sub,m	1	N
JA-03	anus	1.5K	ep,d,sub,m	1	N
JA-04	anus	1.5K	ep,d,sub,m	1	N
JA-05	tonsil	1.5K	ep,d,sub,m,mu,g,a,v	1	N
JA-06	prostate	6K	ep,d,sub,p,m,a,v	1	N
JA-07	bowel	6K	ep,d,sub,ad,m,p,me,a,v	1	N
JA-08	bowel	7.5K	ep, d, sub, ad, m, p, me, a, v	2	N
JA-09	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-10	abdominal hernia	3K	ep, d, sub, m	1	N
JA-11	parotid	6K	ep, d, sub, m, mu, g, a, v	2	N
JA-12	prostate	4.5K	ep, d, sub, p, m, a, v	1	N
JA-13	anus	3K	ep, d, sub, m	1	N
JA-14	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-15	prostate	4.5K	ep, d, sub, p, m	1	N
JA-16	kidney	7.5K	ep, d, sub, m, p, n	2	N
JA-17	anus	3K	ep, d, sub, m	1	N
JA-18	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-19	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-20	anus	3K	ep, d, sub, m	1	N
JA-21	anus	1.5K	ep, d, sub, m	1	N
JA-22	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-23	anus	4.5K	ep, d, sub, m	2	N
JA-24	hip	15K	ep, d, sub, m, b	2	N
JA-25	osteo	7.5K	ep, d, sub, m, b	1	N
JA-26	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-27	anus	3K	ep, d, sub, m	1	N
JA-28	prostate	3K	ep, d, sub, m, a, v	1	N
JA-29	anus	1.5K	ep, d, sub, m, a, v	1	N
JA-30	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-31	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-32	anus	3K	ep, d, sub, m, a, v	1	N

JA-33	skin carcinoma	1.5K	ep, d, sub	1	N
JA-34	bowel	6K	ep, d, sub, ad, m, p, me, a, v	1	N
JA-35	anus	3K	ep, d, sub, m, a, v	1	N
JA-36	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-37	anus	3K	ep, d, sub, m, a, v	1	N
JA-38	anus	3K	ep, d, sub, m, a, v	1	N
JA-39	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-40	prostate	4.5K	ep, d, sub, m, a, v	1	N
JA-41	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-42	skin graft	1.5K	ep, d, sub	1	N
JA-43	anus	3K	ep, d, sub, m, a, v	1	N
JA-44	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-45	abdominal hernia	3K	ep, d, sub, m	1	N
JA-46	anus	3K	ep, d, sub, m, a, v	1	N
JA-47	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-48	anus	1.5K	ep, d, sub, m, a, v	1	N
JA-49	bowel	6K	ep, d, sub, ad, m, p, me, a, v	1	N
JA-50	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	2	N
JA-51	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-52	bladder	6K	ep, d, sub, m, p	1	N
JA-53	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	2	N
JA-54	anus	3K	ep, d, sub, m, a, v	1	N
JA-55	anus	3K	ep, d, sub, m, a, v	1	N
JA-56	hernia	3K	ep, d, sub, m	1	N
JA-57	anus	3K	ep, d, sub, m, a, v	1	N
JA-58	skin graft	1.5K	ep, d, sub	1	N
JA-59	anus	4.5K	ep, d, sub, m, a, v	1	N
JA-60	prostate	4.5K	ep, d, sub, p, m, a, v	1	N
JA-61	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-62	tonsil	1.5K	ep, d, sub, m, mu, g, a, v	1	N
JA-63	thyroid	3K	ep, d, sub, m, mu, g, a, v	1	N
JA-64	knuckle amputation	2.1K	ep, d, sub, m, b	1	N
JA-65	anus	1.5K	ep, d, sub, m, a, v	1	N
JA-66	anus	1.5K	ep, d, sub, m, a, v	1	N
JA-67	skin graft	1.5K	ep, d, sub	1	N
JA-68	prostate	3.6K	ep, d, sub, p, m, a, v	1	N
JA-69	hernia	2.1K	ep, d, sub, m	1	N
JA-70	thyroid	3K	ep, d, sub, m, mu, g, a, v	1	N
JA-71	wound debridement	2.1K	ep, d, sub, m	1	N
JA-72	knuckle debridement	2.1K	ep, d, sub, m, b	1	N
JA-73	anus	1.5K	ep, d, sub, m, a, v	1	N
JA-74	prostate	3K	ep, d, sub, p, m, a, v	1	N
JA-75	thyroid	3K	ep, d, sub, m, mu, g, a, v	1	N
JA-76	prostate	2.4K	ep, d, sub, p, m, a, v	1	N
JA-77	anus	3K	ep, d, sub, m, a, v	1	N
JA-78	wound debridement	2.4K	ep, d, sub, m	1	N
JA-79	knuckle debridement	3K	ep, d, sub, m, b	1	N
JA-80	anus	1.5K	ep, d, sub, m, a, v	1	N
JA-81	ganglion	1.5K	ep, d, sub, ad, m, p	1	N
JA-82	prostate	3.6K	ep, d, sub, p, m, a, v	1	N
JA-83	anus	1.5K	ep, d, sub, m, a, v	1	N
JA-84	thyroid	2.4K	ep, d, sub, m, mu, g, a, v	1	N
JA-85	leg amputation	6K	ep, d, sub, m, a, v, b	1	N
JA-86	wound debridement	1.5K	ep, d, sub, m	1	N
JA-87	hernia	2.1K	ep, d, sub, m	1	N
JA-88	anus	1.8K	ep, d, sub, m, a, v	1	N
JA-89	leg amputation	4.5K	ep, d, sub, m, a, v, b	1	N

Ref. Efficacy Response Data Listing, appendix 12.2.4.

Key: epithelial (ep); dermus (d); subcutaneous (sub); muscle (m), adipose (ad), peritoneum (p); mucus (mu); mesentary (me); gland (g); bone marrow (b); artery (a); vein (v); nephrous (n)

12.2.4 Efficacy Response Data Listing

Efficacy Response Data Listings							
Patient No.	CT (min)	Dose (IU)	IPO	POB	POI	Lab	VS
CV01	4	6K	Y	N	N	NC	NC
CV02	6	9K	N	N	N	NC	NC
CV03	3	7.5K	Y	N	N	NC	NC
CV04	2	7.5K	Y	N	N	NC	NC
CV05	2	7.5K	Y	N	N	NC	NC
CV06	1	6K	Y	N	N	NC	NC
CV07	1	6K	Y	N	N	NC	NC
CV08	7	12K	N	N	N	NC	NC
CV09	1	3K	Y	N	N	NC	NC
CV10	2	6K	Y	N	N	NC	NC
CV11	1	7.5K	Y	N	N	NC	NC
CV12	2	4.5K	Y	N	N	NC	NC
CV13	1	4.5K	Y	N	N	NC	NC
CV14	7	15K	N	N	N	NC	NC
CV15	1	6K	Y	N	N	NC	NC
CV16	1	4.2K	Y	N	N	NC	NC
CV17	1	3K	Y	N	N	NC	NC
CV18	1	3K	Y	N	N	NC	NC
CV19	1	3K	Y	N	N	NC	NC
CV20	1	3.9K	Y	N	N	NC	NC
CV21	1	3K	Y	N	N	NC	NC
JA01	1	7.5K	Y	N	N	NC	NC
JA02	1	1.5K	Y	N	N	NC	NC
JA03	1	1.5K	Y	N	N	NC	NC
JA04	1	1.5K	Y	N	N	NC	NC
JA05	1	1.5K	Y	N	N	NC	NC
JA06	1	6K	Y	N	N	NC	NC
JA07	1	6K	Y	N	N	NC	NC
JA08	2	7.5K	Y	N	N	NC	NC
JA09	1	1.5K	Y	N	N	NC	NC
JA10	1	3K	Y	N	N	NC	NC
JA11	2	6K	Y	N	N	NC	NC
JA12	1	4.5K	Y	N	N	NC	NC
JA13	1	3K	Y	N	N	NC	NC
JA14	1	1.5K	Y	N	N	NC	NC
JA15	1	4.5K	Y	N	N	NC	NC
JA16	2	7.5K	Y	N	N	NC	NC
JA17	1	3K	Y	N	N	NC	NC
JA18	1	1.5K	Y	N	N	NC	NC
JA19	1	1.5K	Y	N	N	NC	NC
JA20	1	3K	Y	N	N	NC	NC
JA21	1	1.5K	Y	N	N	NC	NC
JA22	1	1.5K	Y	N	N	NC	NC
JA23	2	4.5K	Y	N	N	NC	NC
JA24	2	1.2K	Y	N	N	NC	NC
JA25	1	7.5K	Y	N	N	NC	NC
JA26	1	1.5K	Y	N	N	NC	NC
JA27	1	3K	Y	N	N	NC	NC
JA28	1	3KK	Y	N	N	NC	NC

JA29	1	1.5K	Y	N	N	NC	NC
JA30	1	1.5K	Y	N	N	NC	NC
JA31	1	1.5K	Y	N	N	NC	NC
JA32	1	3K	Y	N	N	NC	NC
JA33	1	3K	Y	N	N	NC	NC
JA34	1	6K	Y	N	N	NC	NC
JA35	1	3K	Y	N	N	NC	NC
JA36	1	1.5K	Y	N	N	NC	NC
JA37	1	3K	Y	N	N	NC	NC
JA38	1	3K	Y	N	N	NC	NC
JA39	1	1.5K	Y	N	N	NC	NC
JA40	1	4.5K	Y	N	N	NC	NC
JA41	1	1.5K	Y	N	N	NC	NC
JA42	1	1.5K	Y	N	N	NC	NC
JA43	1	3K	Y	N	N	NC	NC
JA44	1	1.5K	Y	N	N	NC	NC
JA45	1	3K	Y	N	N	NC	NC
JA46	1	3K	Y	N	N	NC	NC
JA47	1	1.5K	Y	N	N	NC	NC
JA48	1	1.5K	Y	N	N	NC	NC
JA49	2	6K	Y	N	N	NC	NC
JA50	1	1.5K	Y	N	N	NC	NC
JA51	1	1.5K	Y	N	N	NC	NC
JA52	2	6K	Y	N	N	NC	NC
JA53	1	1.5K	Y	N	N	NC	NC
JA54	1	3K	Y	N	N	NC	NC
JA55	1	3K	Y	N	N	NC	NC
JA56	1	3K	Y	N	N	NC	NC
JA57	1	3K	Y	N	N	NC	NC
JA58	1	1.5K	Y	N	N	NC	NC
JA59	1	4.5K	Y	N	N	NC	NC
JA60	1	4.5K	Y	N	N	NC	NC
JA61	1	1.5K	Y	N	N	NC	NC
JA62	1	1.5K	Y	N	N	NC	NC
JA63	1	3K	Y	N	N	NC	NC
JA64	1	2.1K	Y	N	N	NC	NC
JA65	1	1.5K	Y	N	N	NC	NC
JA66	1	1.5K	Y	N	N	NC	NC
JA67	1	1.5K	Y	N	N	NC	NC
JA68	1	3.6K	Y	N	N	NC	NC
JA69	1	2.1K	Y	N	N	NC	NC
JA70	1	3K	Y	N	N	NC	NC
JA71	1	2.1K	Y	N	N	NC	NC
JA72	1	2.1K	Y	N	N	NC	NC
JA73	1	1.5K	Y	N	N	NC	NC
JA74	1	3K	Y	N	N	NC	NC
JA75	1	3K	Y	N	N	NC	NC
JA76	1	2.4K	Y	N	N	NC	NC
JA77	1	1.5K	Y	N	N	NC	NC
JA78	1	2.4K	Y	N	N	NC	NC
JA79	1	3K	Y	N	N	NC	NC
JA80	1	1.5K	Y	N	N	NC	NC
JA81	1	1.5K	Y	N	N	NC	NC

JA82	1	3.6K	Y	N	N	NC	NC
JA83	1	1.5K	Y	N	N	NC	NC
JA84	1	2.4K	Y	N	N	NC	NC
JA85	1	6K	Y	N	N	NC	NC
JA86	1	1.5K	Y	N	N	NC	NC
JA87	1	2.1K	Y	N	N	NC	NC
JA88	1	1.8K	Y	N	N	NC	NC
JA89	1	4.5K	Y	N	N	NC	NC
SA01	3	12K	Y	N	N	NC	NC
SA02	2	9K	Y	N	N	NC	NC
SA03	1	6K	Y	N	N	NC	NC
SA04	3	6K	Y	N	N	NC	NC
SA05	2	1.5K	Y	N	N	NC	NC
SA06	3	9K	Y	N	N	NC	NC
SA07	1	2.1K	Y	N	N	NC	NC
SA08	1	6K	Y	N	N	NC	NC
SA09	1	1.5K	Y	N	N	NC	NC
SA10	1	3K	Y	N	N	NC	NC

CT – clotting time
IPO – investigational product only
NC – no change
POB – post-operative bleeding
POI – post-operative infection
VS – vital sign