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Table 1.1.1  
Summary of Patient Demographics and Baseline Characteristics  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total	P-value
Number of Patients	882	443	1325	
Age (yrs)				
N	882	443	1325	
4 to <13	50 ( 6%)	20 ( 5%)	70 ( 5%)	0.739
13 to <65	778 ( 88%)	396 ( 89%)	1174 ( 89%)	
65 to <75	43 ( 5%)	23 ( 5%)	66 ( 5%)	
>=75	11 ( 1%)	4 ( 1%)	15 ( 1%)	
MEAN	36.2	36.5	36.3	
SEM	0.52	0.73	0.42	
MEDIAN	33.0	33.0	33.0	
MIN				
MAX				
Weight (kg)				
N	879	438	1317	
MEAN	72.3	70.9	71.9	0.160
SEM	0.62	0.86	0.51	
MEDIAN	72.0	69.6	70.9	
MIN				
MAX				

The two-sided p-values for age group, sex, race and stratification are from a Cochran-Mantel-Haenszel test adjusting for center effects. The two-sided p-value for weight is from an ANOVA with treatment, center, and strata effects.

Table 1.1.1  
Summary of Patient Demographics and Baseline Characteristics  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total	P-value
<b>Sex</b>				
FEMALE	464 ( 53%)	259 ( 58%)	723 ( 55%)	0.043
MALE	418 ( 47%)	184 ( 42%)	602 ( 45%)	
<b>Race</b>				0.815
WHITE	647 ( 73%)	330 ( 74%)	977 ( 74%)	
BLACK	74 ( 8%)	34 ( 8%)	108 ( 8%)	
ASIAN	44 ( 5%)	27 ( 6%)	71 ( 5%)	
HISPANIC	94 ( 11%)	42 ( 9%)	136 ( 10%)	
OTHER	23 ( 3%)	10 ( 2%)	33 ( 2%)	
<b>Stratification</b>				0.955
Simple Procedure	675 ( 77%)	338 ( 76%)	1013 ( 76%)	
Complex Procedure	207 ( 23%)	105 ( 24%)	312 ( 24%)	
<b>Temperature (c)</b>				
N	881	443	1324	
MEAN	36.6	36.6	36.6	
SEM	0.02	0.02	0.02	
MEDIAN	36.6	36.6	36.6	
MIN				
MAX				

The two-sided p-values for age group, sex, race and stratification are from a Cochran-Mantel-Haenszel test adjusting for center effects. The two-sided p-value for weight is from an ANOVA with treatment, center, and strata effects.

Table 1.1.2  
 Summary of Patient Demographics and Baseline Characteristics by Age Group  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Number of Patients	50	20	70
Age (yrs)			
N	50	20	70
MEAN	8.8	8.5	8.7
SEM	0.37	0.50	0.30
MEDIAN	9.5	9.0	9.0
MIN			
MAX			
Weight (kg)			
N	50	20	70
MEAN	39.3	31.9	37.2
SEM	2.64	2.05	2.01
MEDIAN	36.4	32.5	34.1
MIN			
MAX			
Sex			
FEMALE	21 ( 42%)	13 ( 65%)	34 ( 49%)
MALE	29 ( 58%)	7 ( 35%)	36 ( 51%)



Table 1.1.2  
Summary of Patient Demographics and Baseline Characteristics by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4X Articaine HCl/ 1:100,000 Epinephrine	2X Lidocaine HCl/ 1:100,000 Epinephrine	Total
<b>Race</b>			
WHITE	10 ( 20%)	5 ( 25%)	15 ( 21%)
BLACK	6 ( 12%)	0	6 ( 9%)
ASIAN	2 ( 4%)	1 ( 5%)	3 ( 4%)
HISPANIC	32 ( 64%)	14 ( 70%)	46 ( 66%)
<b>Stratification</b>			
Simple Procedure	43 ( 86%)	18 ( 90%)	61 ( 87%)
Complex Procedure	7 ( 14%)	2 ( 10%)	9 ( 13%)
<b>Temperature (c)</b>			
N	50	20	70
MEAN	36.8	36.7	36.8
SEM	0.05	0.11	0.05
MEDIAN	36.8	36.8	36.8
MIN			
MAX			

Table 1.1.2  
Summary of Patient Demographics and Baseline Characteristics by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Number of Patients	778	396	1174
Age (yrs)			
N	778	396	1174
MEAN	35.6	35.7	35.6
SEM	0.43	0.61	0.35
MEDIAN	33.0	33.0	33.0
MIN			
MAX			
Weight (kg)			
N	775	392	1167
MEAN	74.3	72.4	73.6
SEM	0.59	0.81	0.48
MEDIAN	72.7	70.5	72.0
MIN			
MAX			
Sex			
FEMALE	413 ( 53%)	232 ( 59%)	645 ( 55%)
MALE	365 ( 47%)	164 ( 41%)	529 ( 45%)

Table 1.1.2  
Summary of Patient Demographics and Baseline Characteristics by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
<b>Race</b>			
WHITE	588 ( 76%)	301 ( 76%)	889 ( 76%)
BLACK	65 ( 8%)	32 ( 8%)	97 ( 8%)
ASIAN	41 ( 5%)	26 ( 7%)	67 ( 6%)
HISPANIC	61 ( 8%)	27 ( 7%)	88 ( 7%)
OTHER	23 ( 3%)	10 ( 3%)	33 ( 3%)
<b>Stratification</b>			
Simple Procedure	597 ( 77%)	301 ( 76%)	898 ( 76%)
Complex Procedure	181 ( 23%)	95 ( 24%)	276 ( 24%)
<b>Temperature (c)</b>			
N	777	396	1173
MEAN	36.6	36.6	36.6
SEM	0.02	0.03	0.02
MEDIAN	36.6	36.6	36.6
MIN			
MAX			

Table 1.1.2  
Summary of Patient Demographics and Baseline Characteristics by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Number of Patients	43	23	66
Age (yrs)			
N	43	23	66
MEAN	69.1	68.8	69.0
SEM	0.48	0.61	0.38
MEDIAN	69.0	68.0	68.0
MIN			
MAX			
Weight (kg)			
N	43	22	65
MEAN	76.0	76.4	76.1
SEM	2.40	3.70	2.00
MEDIAN	75.0	71.6	74.5
MIN			
MAX			
Sex			
FEMALE	25 ( 58%)	13 ( 57%)	38 ( 58%)
MALE	18 ( 42%)	10 ( 43%)	28 ( 42%)

Table 1.1.2  
 Summary of Patient Demographics and Baseline Characteristics by Age Group  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Age Group: 65 to <75

	4X Articaine HCl/ 1:100,000 Epinephrine	2X Lidocaine HCl/ 1:100,000 Epinephrine	Total
<b>Race</b>			
WHITE	39 ( 91%)	21 ( 91%)	60 ( 91%)
BLACK	2 ( 5%)	1 ( 4%)	3 ( 5%)
ASIAN	1 ( 2%)	0	1 ( 2%)
HISPANIC	1 ( 2%)	1 ( 4%)	2 ( 3%)
<b>Stratification</b>			
Simple Procedure	28 ( 65%)	18 ( 78%)	46 ( 70%)
Complex Procedure	15 ( 35%)	5 ( 22%)	20 ( 30%)
<b>Temperature (c)</b>			
N	43	23	66
MEAN	36.3	36.4	36.3
SEM	0.13	0.11	0.09
MEDIAN	36.5	36.4	36.5
MIN			
MAX			

Table 1.1.2  
 Summary of Patient Demographics and Baseline Characteristics by Age Group  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Number of Patients	11	4	15
Age (yrs)			
N	11	4	15
MEAN	76.3	77.0	76.5
SEM	0.56	0.00	0.41
MEDIAN	75.0	77.0	77.0
MIN			
MAX			
Weight (kg)			
N	11	4	15
MEAN	73.2	85.7	76.5
SEM	4.79	9.07	4.35
MEDIAN	70.5	89.8	75.0
MIN			
MAX			
Sex			
FEMALE	5 ( 45%)	1 ( 25%)	6 ( 40%)
MALE	6 ( 55%)	3 ( 75%)	9 ( 60%)

Table 1.1.2  
 Summary of Patient Demographics and Baseline Characteristics by Age Group  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
<b>Race</b>			
WHITE	10 ( 91%)	3 ( 75%)	13 ( 87%)
BLACK	1 ( 9%)	1 ( 25%)	2 ( 13%)
<b>Stratification</b>			
Simple Procedure	7 ( 64%)	1 ( 25%)	8 ( 53%)
Complex Procedure	4 ( 36%)	3 ( 75%)	7 ( 47%)
<b>Temperature (c)</b>			
N	11	4	15
MEAN	36.4	36.2	36.4
SEM	0.16	0.20	0.13
MEDIAN	36.5	36.3	36.4
MIN			
MAX			

Table 1.1.3  
 Summary of Patient Demographics and Baseline Characteristics by Race  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Race: WHITE

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Number of Patients	647	330	977
Age (yrs)			
N	647	330	977
4 to <13	10 ( 2%)	5 ( 2%)	15 ( 2%)
13 to <65	588 ( 91%)	301 ( 91%)	889 ( 91%)
65 to <75	39 ( 6%)	21 ( 6%)	60 ( 6%)
>=75	10 ( 2%)	3 ( 1%)	13 ( 1%)
MEAN	38.5	38.5	38.5
SEM	0.60	0.84	0.49
MEDIAN	35.0	36.0	35.0
MIN			
MAX			
Weight (kg)			
N	644	325	969
MEAN	75.0	72.8	74.2
SEM	0.67	0.95	0.55
MEDIAN	74.1	70.5	72.7
MIN			
MAX			



Table 1.1.3  
Summary of Patient Demographics and Baseline Characteristics by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: WHITE

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	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Sex			
FEMALE	320 ( 49%)	190 ( 58%)	510 ( 52%)
MALE	327 ( 51%)	140 ( 42%)	467 ( 48%)
Stratification			
Simple Procedure	488 ( 75%)	254 ( 77%)	742 ( 76%)
Complex Procedure	159 ( 25%)	76 ( 23%)	235 ( 24%)
Temperature (c)			
N	646	330	976
MEAN	36.5	36.5	36.5
SEM	0.02	0.03	0.02
MEDIAN	36.6	36.6	36.6
MIN			
MAX			

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Table 1.1.3  
Summary of Patient Demographics and Baseline Characteristics by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: BLACK

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Number of Patients	74	34	108
Age (yrs)			
N	74	34	108
4 to <13	6 ( 8%)	0	6 ( 6%)
13 to <65	65 ( 88%)	32 ( 94%)	97 ( 90%)
65 to <75	2 ( 3%)	1 ( 3%)	3 ( 3%)
>=75	1 ( 1%)	1 ( 3%)	2 ( 2%)
MEAN	35.9	40.0	37.2
SEM	1.67	2.23	1.35
MEDIAN	35.0	39.0	36.0
MIN			
MAX			
Weight (kg)			
N	74	34	108
MEAN	73.1	78.4	74.8
SEM	2.38	2.01	1.76
MEDIAN	73.2	79.1	75.9
MIN			
MAX			

Table 1.1.3  
 Summary of Patient Demographics and Baseline Characteristics by Race  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Race: BLACK

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
<b>Sex</b>			
FEMALE	50 ( 68%)	25 ( 74%)	75 ( 69%)
MALE	24 ( 32%)	9 ( 26%)	33 ( 31%)
<b>Stratification</b>			
Simple Procedure	53 ( 72%)	22 ( 65%)	75 ( 69%)
Complex Procedure	21 ( 28%)	12 ( 35%)	33 ( 31%)
<b>Temperature (c)</b>			
N	74	34	108
MEAN	36.7	36.7	36.7
SEM	0.07	0.10	0.06
MEDIAN	36.8	36.7	36.8
MIN			
MAX			

Table 1.1.3  
 Summary of Patient Demographics and Baseline Characteristics by Race  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Race: ASIAN

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
<b>Sex</b>			
FEMALE	21 ( 48%)	10 ( 37%)	31 ( 44%)
MALE	23 ( 52%)	17 ( 63%)	40 ( 56%)
<b>Stratification</b>			
Simple Procedure	37 ( 84%)	21 ( 78%)	58 ( 82%)
Complex Procedure	7 ( 16%)	6 ( 22%)	13 ( 18%)
<b>Temperature (c)</b>			
N	44	27	71
MEAN	36.7	36.7	36.7
SEM	0.07	0.10	0.06
MEDIAN	36.6	36.9	36.7
MIN			
MAX			

Table 1.1.3  
Summary of Patient Demographics and Baseline Characteristics by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: ASIAN

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Number of Patients	44	27	71
Age (yrs)			
N	44	27	71
4 to <13	2 ( 5%)	1 ( 4%)	3 ( 4%)
13 to <65	41 ( 93%)	26 ( 96%)	67 ( 94%)
65 to <75	1 ( 2%)	0	1 ( 1%)
MEAN	30.2	28.5	29.5
SEM	1.67	1.84	1.24
MEDIAN	27.0	27.0	27.0
MIN	<hr/>		
MAX	<hr/>		
Weight (kg)			
N	44	27	71
MEAN	63.8	58.9	61.9
SEM	2.15	2.16	1.58
MEDIAN	62.0	60.0	61.4
MIN	<hr/>		
MAX	<hr/>		

Table 1.1.3  
 Summary of Patient Demographics and Baseline Characteristics by Race  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Race: HISPANIC

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
<b>Sex</b>			
FEMALE	60 ( 64%)	29 ( 69%)	89 ( 65%)
MALE	34 ( 36%)	13 ( 31%)	47 ( 35%)
<b>Stratification</b>			
Simple Procedure	76 ( 81%)	34 ( 81%)	110 ( 81%)
Complex Procedure	18 ( 19%)	8 ( 19%)	26 ( 19%)
<b>Temperature (c)</b>			
N	94	42	136
MEAN	36.7	36.7	36.7
SEM	0.05	0.06	0.04
MEDIAN	36.8	36.7	36.7
MIN			
MAX			

Table 1.1.3  
 Summary of Patient Demographics and Baseline Characteristics by Race  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Race: HISPANIC

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Number of Patients	94	42	136
Age (yrs)			
N	94	42	136
4 to <13	32 ( 34%)	14 ( 33%)	46 ( 34%)
13 to <65	61 ( 65%)	27 ( 64%)	88 ( 65%)
65 to <75	1 ( 1%)	1 ( 2%)	2 ( 1%)
MEAN	24.7	23.7	24.4
SEM	1.49	2.16	1.22
MEDIAN	24.0	24.5	24.0
MIN			
MAX			
Weight (kg)			
N	94	42	136
MEAN	60.0	59.5	59.8
SEM	2.30	3.86	1.98
MEDIAN	59.1	60.9	59.1
MIN			
MAX			

Table 1.1.3  
Summary of Patient Demographics and Baseline Characteristics by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Number of Patients	23	10	33
Age (yrs)			
N	23	10	33
13 to <65	23 (100%)	10 (100%)	33 (100%)
MEAN	30.3	34.3	31.5
SEM	2.27	4.40	2.06
MEDIAN	27.0	29.0	27.0
MIN			
MAX			
Weight (kg)			
N	23	10	33
MEAN	63.8	64.0	63.8
SEM	2.53	2.32	1.88
MEDIAN	61.4	63.6	61.4
MIN			
MAX			
Sex			
FEMALE	13 ( 57%)	5 ( 50%)	18 ( 55%)
MALE	10 ( 43%)	5 ( 50%)	15 ( 45%)



Table 1.1.3  
Summary of Patient Demographics and Baseline Characteristics by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Stratification			
Simple Procedure	21 ( 91%)	7 ( 70%)	28 ( 85%)
Complex Procedure	2 ( 9%)	3 ( 30%)	5 ( 15%)
Temperature (c)			
N	23	10	33
MEAN	36.7	36.8	36.7
SEM	0.11	0.15	0.09
MEDIAN	36.6	36.8	36.7
MIN			
MAX			

Table 1.1.4  
 Summary of Patient Demographics and Baseline Characteristics by Gender  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Gender: FEMALE

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Number of Patients	464	259	723
Age (yrs)			
N	464	259	723
4 to <13	21 ( 5%)	13 ( 5%)	34 ( 5%)
13 to <65	413 ( 89%)	232 ( 90%)	645 ( 89%)
65 to <75	25 ( 5%)	13 ( 5%)	38 ( 5%)
>=75	5 ( 1%)	1 ( <1%)	6 ( 1%)
MEAN	37.2	36.2	36.9
SEM	0.71	0.95	0.57
MEDIAN	35.0	33.0	34.0
MIN			
MAX			
Weight (kg)			
N	462	255	717
MEAN	66.3	65.0	65.8
SEM	0.76	1.01	0.61
MEDIAN	64.0	62.3	63.6
MIN			
MAX			

Table 1.1.4  
Summary of Patient Demographics and Baseline Characteristics by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: FEMALE

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
<b>Race</b>			
WHITE	320 ( 69%)	190 ( 73%)	510 ( 71%)
BLACK	50 ( 11%)	25 ( 10%)	75 ( 10%)
ASIAN	21 ( 5%)	10 ( 4%)	31 ( 4%)
HISPANIC	60 ( 13%)	29 ( 11%)	89 ( 12%)
OTHER	13 ( 3%)	5 ( 2%)	18 ( 2%)
<b>Stratification</b>			
Simple Procedure	356 ( 77%)	207 ( 80%)	563 ( 78%)
Complex Procedure	108 ( 23%)	52 ( 20%)	160 ( 22%)
<b>Temperature (c)</b>			
N	464	259	723
MEAN	36.6	36.6	36.6
SEM	0.02	0.03	0.02
MEDIAN	36.7	36.6	36.7
MIN			
MAX			

Table 1.1.4  
 Summary of Patient Demographics and Baseline Characteristics by Gender  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Gender: MALE

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
Number of Patients	418	184	602
Age (yrs)			
N	418	184	602
4 to <13	29 ( 7%)	7 ( 4%)	36 ( 6%)
13 to <65	365 ( 87%)	164 ( 89%)	529 ( 88%)
65 to <75	18 ( 4%)	10 ( 5%)	28 ( 5%)
>=75	6 ( 1%)	3 ( 2%)	9 ( 1%)
MEAN	35.1	37.0	35.7
SEM	0.76	1.14	0.63
MEDIAN	31.0	32.0	32.0
MIN			
MAX			
Weight (kg)			
N	417	183	600
MEAN	79.1	79.1	79.1
SEM	0.90	1.30	0.74
MEDIAN	78.0	78.0	78.0
MIN			
MAX			

Table 1.1.4  
 Summary of Patient Demographics and Baseline Characteristics by Gender  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Gender: MALE

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
<b>Race</b>			
WHITE	327 ( 78%)	140 ( 76%)	467 ( 78%)
BLACK	24 ( 6%)	9 ( 5%)	33 ( 5%)
ASIAN	23 ( 6%)	17 ( 9%)	40 ( 7%)
HISPANIC	34 ( 8%)	13 ( 7%)	47 ( 8%)
OTHER	10 ( 2%)	5 ( 3%)	15 ( 2%)
<b>Stratification</b>			
Simple Procedure	319 ( 76%)	131 ( 71%)	450 ( 75%)
Complex Procedure	99 ( 24%)	53 ( 29%)	152 ( 25%)
<b>Temperature (c)</b>			
N	417	184	601
MEAN	36.5	36.5	36.5
SEM	0.03	0.04	0.02
MEDIAN	36.6	36.6	36.6
MIN			
MAX			

Table 1.2.1  
Summary of Patient Demographics and Baseline Characteristics  
Protocols S96001.02 and S96002.01  
All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total	P-value
Number of Patients	724	359	1083	
Age (yrs)				
N	724	359	1083	
4 to <13	47 ( 6%)	18 ( 5%)	65 ( 6%)	0.698
13 to <65	630 ( 87%)	316 ( 88%)	946 ( 87%)	
65 to <75	37 ( 5%)	21 ( 6%)	58 ( 5%)	
>=75	10 ( 1%)	4 ( 1%)	14 ( 1%)	
MEAN	36.8	37.1	36.9	
SEM	0.58	0.82	0.47	
MEDIAN	34.0	33.0	34.0	
MIN				
MAX				
Weight (kg)				
N	721	354	1075	
MEAN	72.6	71.6	72.3	0.429
SEM	0.72	0.99	0.58	
MEDIAN	72.7	70.5	71.8	
MIN				
MAX				

The two-sided p-values for age group, sex, race and stratification are from a Cochran-Mantel-Haenszel test adjusting for center effects. The two-sided p-value for weight is from an ANOVA with treatment, center, and strata effects.

Table 1.2.1  
 Summary of Patient Demographics and Baseline Characteristics  
 Protocols S96001.02 and S96002.01  
 All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total	P-value
<b>Sex</b>				
FEMALE	384 ( 53%)	208 ( 58%)	592 ( 55%)	0.127
MALE	340 ( 47%)	151 ( 42%)	491 ( 45%)	
<b>Race</b>				
WHITE	504 ( 70%)	250 ( 70%)	754 ( 70%)	0.586
BLACK	68 ( 9%)	31 ( 9%)	99 ( 9%)	
ASIAN	36 ( 5%)	26 ( 7%)	62 ( 6%)	
HISPANIC	94 ( 13%)	42 ( 12%)	136 ( 13%)	
OTHER	22 ( 3%)	10 ( 3%)	32 ( 3%)	
<b>Stratification</b>				
Simple Procedure	560 ( 77%)	278 ( 77%)	838 ( 77%)	0.916
Complex Procedure	164 ( 23%)	81 ( 23%)	245 ( 23%)	
<b>Temperature (c)</b>				
N	723	359	1082	
MEAN	36.6	36.6	36.6	
SEM	0.02	0.03	0.02	
MEDIAN	36.7	36.6	36.7	
MIN				
MAX				

The two-sided p-values for age group, sex, race and stratification are from a Cochran-Mantel-Haenszel test adjusting for center effects. The two-sided p-value for weight is from an ANOVA with treatment, center, and strata effects.

Table 1.3.1  
Summary of Patient Demographics and Baseline Characteristics  
Protocol S96001.02UK  
All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total	P-value
Number of Patients	158	84	242	
Age (yrs)				
N	158	84	242	
4 to <13	3 ( 2%)	2 ( 2%)	5 ( 2%)	0.712
13 to <65	148 ( 94%)	80 ( 95%)	228 ( 94%)	
65 to <75	6 ( 4%)	2 ( 2%)	8 ( 3%)	
>=75	1 ( 1%)	0	1 (<1%)	
MEAN	33.7	34.0	33.8	
SEM	1.19	1.56	0.95	
MEDIAN	30.5	31.0	31.0	
MIN				
MAX				
Weight (kg)				
N	158	84	242	
MEAN	71.3	67.9	70.1	0.126
SEM	1.13	1.62	0.93	
MEDIAN	71.3	65.6	70.0	
MIN				
MAX				

The two-sided p-values for age group, sex, race and stratification are from a Cochran-Mantel-Haenszel test adjusting for center effects. The two-sided p-value for weight is from an ANOVA with treatment, center, and strata effects.



Table 1.3.1  
Summary of Patient Demographics and Baseline Characteristics  
Protocol S96001.02UK  
All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total	P-value
<b>Sex</b>				
FEMALE	80 ( 51%)	51 ( 61%)	131 ( 54%)	0.154
MALE	78 ( 49%)	33 ( 39%)	111 ( 46%)	
<b>Race</b>				
WHITE	143 ( 91%)	80 ( 95%)	223 ( 92%)	0.309
BLACK	6 ( 4%)	3 ( 4%)	9 ( 4%)	
ASIAN	8 ( 5%)	1 ( 1%)	9 ( 4%)	
OTHER	1 ( 1%)	0	1 ( <1%)	
<b>Stratification</b>				
Simple Procedure	115 ( 73%)	60 ( 71%)	175 ( 72%)	0.848
Complex Procedure	43 ( 27%)	24 ( 29%)	67 ( 28%)	
<b>Temperature (c)</b>				
N	158	84	242	
MEAN	36.4	36.4	36.4	
SEM	0.05	0.05	0.04	
MEDIAN	36.4	36.4	36.4	
MIN				
MAX				

The two-sided p-values for age group, sex, race and stratification are from a Cochran-Mantel-Haenszel test adjusting for center effects. The two-sided p-value for weight is from an ANOVA with treatment, center, and strata effects.

Table 1.4.1  
Summary of Patient Demographics and Baseline Characteristics  
Protocol S97001  
All Treated Patients

---

4% Articaine HCl/ 1:200,000 Epinephrine	
Number of Patients	20
Age (yrs)	
13 to <65	20 (100%)
N	20
MEAN	32.6
SEM	1.69
MEDIAN	33.0
MIN	
MAX	—
Weight (kg)	
N	20
MEAN	70.7
SEM	2.44
MEDIAN	70.2
MIN	
MAX	—
Sex	
FEMALE	10 ( 50%)
MALE	10 ( 50%)
Race	
WHITE	5 ( 25%)
BLACK	3 ( 15%)
HISPANIC	12 ( 60%)

---

Percents are based on the total number of treated subjects.

Table 1.4.1  
Summary of Patient Demographics and Baseline Characteristics  
Protocol S97001  
All Treated Patients

---

4% Articaine HCl/  
1:200,000 Epinephrine

---

Temperature (c)

N	20
MEAN	36.6
SEM	0.08
MEDIAN	36.7
MIN	
MAX	

---

Percents are based on the total number of treated subjects.

Table 1.4.2  
Summary of Patient Demographics and Baseline Characteristics by Age Group  
Protocol S97001  
All Treated Patients

Age Group: 13 to <65

---

	4% Articaine HCl/ 1:200,000 Epinephrine
Number of Patients	20
Age (yrs)	
N	20
MEAN	32.6
SEM	1.69
MEDIAN	33.0
MIN	
MAX	
Weight (kg)	
N	20
MEAN	70.7
SEM	2.44
MEDIAN	70.2
MIN	
MAX	
Sex	
FEMALE	10 ( 50%)
MALE	10 ( 50%)
Race	
WHITE	5 ( 25%)
BLACK	3 ( 15%)
HISPANIC	12 ( 60%)

---

Percents are based on the total number of treated subjects.

Table 1.4.2  
Summary of Patient Demographics and Baseline Characteristics by Age Group  
Protocol S97001  
All Treated Patients

Age Group: 13 to <65

---

4X Articaine HCl/  
1:200,000 Epinephrine

---

Temperature (c)

N	20
MEAN	36.6
SEM	0.08
MEDIAN	36.7
MIN	
MAX	

---

Percents are based on the total number of treated subjects.

Table 1.4.3  
Summary of Patient Demographics and Baseline Characteristics by Race  
Protocol S97001  
All Treated Patients

Race: WHITE

---

	4% Articaine HCl/ 1:200,000 Epinephrine
Number of Patients	5
Age (yrs)	
13 to <65	5 (100%)
N	5
MEAN	38.8
SEN	4.41
MEDIAN	42.0
MIN	
MAX	
Weight (kg)	
N	5
MEAN	75.3
SEN	5.74
MEDIAN	79.1
MIN	
MAX	
Sex	
FEMALE	1 ( 20%)
MALE	4 ( 80%)

---

Percents are based on the total number of treated subjects.

Table 1.4.3  
Summary of Patient Demographics and Baseline Characteristics by Race  
Protocol S97001  
All Treated Patients

Race: WHITE

---

4X Articaine HCl/  
1:200,000 Epinephrine

---

Temperature (c)

N	5
MEAN	36.5
SEM	0.21
MEDIAN	36.5
MIN	
MAX	

---

Percents are based on the total number of treated subjects.

Table 1.4.3  
Summary of Patient Demographics and Baseline Characteristics by Race  
Protocol S97001  
All Treated Patients

Race: BLACK

---

	4% Articaine HCl/ 1:200,000 Epinephrine
Number of Patients	3
Age (yrs)	
13 to <65	3 (100%)
N	3
MEAN	30.0
SEM	2.65
MEDIAN	29.0
MIN	—
MAX	—
Weight (kg)	
N	3
MEAN	68.6
SEM	4.41
MEDIAN	65.9
MIN	—
MAX	—
Sex	
FEMALE	2 ( 67%)
MALE	1 ( 33%)

---

Percents are based on the total number of treated subjects.



Table 1.4.3  
Summary of Patient Demographics and Baseline Characteristics by Race  
Protocol S97001  
All Treated Patients

Race: BLACK

---

4% Articaine HCl/  
1:200,000 Epinephrine

---

Temperature (c)

N	3
MEAN	36.6
SEM	0.20
MEDIAN	36.4
MIN	
MAX	

---

Percents are based on the total number of treated subjects.

Table 1.4.3  
Summary of Patient Demographics and Baseline Characteristics by Race  
Protocol S97001  
All Treated Patients

Race: HISPANIC

---

	4% Articaine HCl/ 1:200,000 Epinephrine
Number of Patients	12
Age (yrs)	
13 to <65	12 (100%)
N	12
MEAN	30.7
SEM	1.72
MEDIAN	31.0
MIN	
MAX	
Weight (kg)	
N	12
MEAN	69.4
SEM	3.19
MEDIAN	68.6
MIN	
MAX	
Sex	
FEMALE	7 ( 58%)
MALE	5 ( 42%)

---

Percents are based on the total number of treated subjects.

Table 1.4.3  
Summary of Patient Demographics and Baseline Characteristics by Race  
Protocol S97001  
All Treated Patients

Race: HISPANIC

---

4% Articaine HCl/  
1:200,000 Epinephrine

---

Temperature (c)

N	12
MEAN	36.7
SEM	0.08
MEDIAN	36.7
MIN	
MAX	

---

Percents are based on the total number of treated subjects.

Table 1.4.4  
Summary of Patient Demographics and Baseline Characteristics by Gender  
Protocol S97001  
All Treated Patients

Gender: FEMALE

---

4% Articaine HCl/ 1:200,000 Epinephrine	
Number of Patients	10
Age (yrs)	
13 to <65	10 (100%)
N	10
MEAN	30.5
SEM	1.44
MEDIAN	31.0
MIN	
MAX	
Weight (kg)	
N	10
MEAN	65.1
SEM	2.91
MEDIAN	65.5
MIN	
MAX	
Race	
WHITE	1 ( 10%)
BLACK	2 ( 20%)
HISPANIC	7 ( 70%)

---

Percents are based on the total number of treated subjects.

Table 1.4.4  
Summary of Patient Demographics and Baseline Characteristics by Gender  
Protocol S97001  
All Treated Patients

Gender: FEMALE

---

4% Articaine HCl/  
1:200,000 Epinephrine

---

Temperature (c)

N	10
MEAN	36.7
SEM	0.07
MEDIAN	36.7
MIN	
MAX	

---

Percents are based on the total number of treated subjects.

Table 1.4.4  
Summary of Patient Demographics and Baseline Characteristics by Gender  
Protocol S97001  
All Treated Patients

Gender: MALE

---

	4% Articaine HCl/ 1:200,000 Epinephrine
Number of Patients	10
Age (yrs)	
13 to <65	10 (100%)
N	10
MEAN	34.7
SEM	2.99
MEDIAN	34.0
MIN	—
MAX	—
Weight (kg)	
N	10
MEAN	76.3
SEM	3.11
MEDIAN	79.1
MIN	—
MAX	—
Race	
WHITE	4 ( 40%)
BLACK	1 ( 10%)
HISPANIC	5 ( 50%)

---

Percents are based on the total number of treated subjects.

Table 1.4.4  
Summary of Patient Demographics and Baseline Characteristics by Gender  
Protocol S97001  
All Treated Patients

Gender: MALE

---

4% Articaine HCl/  
1:200,000 Epinephrine

---

Temperature (c)

N	10
MEAN	36.6
SEM	0.14
MEDIAN	36.7
MIN	
MAX	

---

Percents are based on the total number of treated subjects.

Table 2.1.1  
Summary of Study Drug Administration by Stratification  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
Number of Subjects	675	207	338	105
Duration of Procedure (minutes)				
N	674	207	336	104
MEAN	36.4	58.3	37.7	52.6
SEM	1.28	3.07	2.01	3.99
MEDIAN	29.0	50.0	30.0	40.5
MIN	-----			
MAX	-----			
MISSING	1	0	2	1
Calculated Total Volume Received (mL)				
N	675	207	338	104
MEAN	2.5	4.2	2.6	4.5
SEM	0.07	0.15	0.09	0.21
MEDIAN	1.7	3.4	1.7	4.3
MIN	-----			
MAX	-----			
MISSING	0	0	0	1



Table 2.1.1  
Summary of Study Drug Administration by Stratification  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	675	207	338	104
MEAN	1.5	2.5	1.5	2.6
SEM	0.04	0.09	0.06	0.12
MEDIAN	1.0	2.0	1.0	2.5
MIN				
MAX				
MISSING	0	0	0	1
<b>Dose (mg/kg)</b>				
N	672	207	333	104
MEAN	1.48	2.36	0.80	1.26
SEM	0.042	0.094	0.031	0.065
MEDIAN	1.11	2.06	0.60	1.16
MIN				
MAX				
MISSING	3	0	5	1

Table 2.1.2  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Number of Subjects</b>	43	7	18	2
<b>Duration of Procedure (minutes)</b>				
N	43	7	18	2
MEAN	15.9	69.3	19.3	56.5
SEM	2.46	19.99	5.19	55.50
MEDIAN	9.0	70.0	9.0	56.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Calculated Total Volume Received (mL)</b>				
N	43	7	18	2
MEAN	1.9	2.5	1.9	2.6
SEM	0.10	0.43	0.23	0.00
MEDIAN	1.7	3.4	1.7	2.6
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.2  
 Summary of Study Drug Administration by Stratification and Age Group  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	43	7	18	2
MEAN	1.1	1.5	1.1	1.5
SEM	0.06	0.25	0.13	0.00
MEDIAN				
MIN				
MAX	2.0	2.0	2.0	1.5
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	43	7	18	2
MEAN	2.37	2.91	1.27	1.43
SEM	0.182	1.009	0.144	0.296
MEDIAN	2.08	2.39	1.22	1.43
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.2  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
Number of Subjects	597	181	301	95
Duration of Procedure (minutes)				
N	596	181	299	95
MEAN	38.6	57.2	39.2	51.9
SEM	1.40	3.29	2.18	4.19
MEDIAN	31.0	46.0	31.0	40.0
MIN				
MAX				
MISSING	1	0	2	0
Calculated Total Volume Received (mL)				
N	597	181	301	94
MEAN	2.5	4.3	2.7	4.6
SEM	0.07	0.16	0.10	0.22
MEDIAN	1.7	3.4	1.7	4.3
MIN				
MAX				
MISSING	0	0	0	1

Table 2.1.2  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	597	181	301	94
MEAN	1.5	2.5	1.6	2.7
SEM	0.04	0.10	0.06	0.13
MEDIAN	1.0	2.0	1.0	2.5
MIN				
MAX				
MISSING	0	0	0	1
<b>Dose (mg/kg)</b>				
N	594	181	297	94
MEAN	1.43	2.38	0.77	1.29
SEM	0.043	0.099	0.031	0.070
MEDIAN	1.08	2.06	0.58	1.18
MIN				
MAX				
MISSING	3	0	4	1

Table 2.1.2  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
Number of Subjects	28	15	18	5
Duration of Procedure (minutes)				
N	28	15	18	4
MEAN	28.6	56.7	25.9	60.8
SEM	4.85	6.12	4.68	12.64
MEDIAN	24.5	57.0	20.0	64.5
MIN				
MAX				
MISSING	0	0	0	1
Calculated Total Volume Received (mL)				
N	28	15	18	5
MEAN	2.0	3.8	2.9	3.7
SEM	0.21	0.43	0.53	0.95
MEDIAN	1.7	3.4	2.1	4.3
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.2  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	28	15	18	5
MEAN	1.2	2.2	1.7	2.2
SEM	0.12	0.25	0.31	0.56
MEDIAN	1.0	2.0	1.3	2.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	28	15	17	5
MEAN	1.10	2.04	0.85	0.88
SEM	0.129	0.212	0.158	0.181
MEDIAN	0.89	1.93	0.51	0.83
MIN				
MAX				
MISSING	0	0	1	0

Table 2.1.2  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
Number of Subjects	7	4	1	3
Duration of Procedure (minutes)				
N	7	4	1	3
MEAN	13.4	98.0	139.0	61.3
SEM	3.13	39.70		29.42
MEDIAN	10.0	64.5	139.0	36.0
MIN				
MAX				
MISSING	0	0	0	0
Calculated Total Volume Received (mL)				
N	7	4	1	3
MEAN	3.6	3.5	1.7	3.7
SEM	1.47	0.82		1.02
MEDIAN	1.7	3.8	1.7	4.3
MIN				
MAX				
MISSING	0	0	0	0



Table 2.1.2  
 Summary of Study Drug Administration by Stratification and Age Group  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	7	4	1	3
MEAN	2.1	2.1	1.0	2.2
SEM	0.87	0.48		0.60
MEDIAN	1.0	2.3	1.0	2.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	7	4	1	3
MEAN	1.77	1.86	0.34	0.93
SEM	0.578	0.248		0.271
MEDIAN	0.97	2.08	0.34	1.02
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: WHITE</b>				
Number of Subjects	9	1	4	1
<b>Duration of Procedure (minutes)</b>				
N	9	1	4	1
MEAN	11.4	22.0	13.3	1.0
SEM	5.42		2.14	
MEDIAN	7.0	22.0	13.5	1.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Calculated Total Volume Received (mL)</b>				
N	9	1	4	1
MEAN	2.0	0.7	1.8	2.6
SEM	0.20		0.61	
MEDIAN	1.7	0.7	1.7	2.6
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4X Articaine HCl/ 1:100,000 Epinephrine		2X Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: WHITE</b>				
<b>Total Number of Cartridges Received</b>				
N	9	1	4	1
MEAN	1.2	0.4	1.1	1.5
SEM	0.12		0.36	
MEDIAN	1.0	0.4	1.0	1.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	9	1	4	1
MEAN	2.56	0.37	1.14	1.13
SEM	0.483		0.403	
MEDIAN	2.22	0.37	1.12	1.13
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: BLACK</b>				
<b>Number of Subjects</b>	4	2		
<b>Duration of Procedure (minutes)</b>				
N	4	2		
MEAN	7.3	87.0		
SEM	0.63	17.00		
MEDIAN	7.0	87.0		
MIN				
MAX				
MISSING	0	0		
<b>Calculated Total Volume Received (mL)</b>				
N	4	2		
MEAN	1.7	3.4		
SEM	0.00	0.00		
MEDIAN	1.7	3.4		
MIN				
MAX				
MISSING	0	0		

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4X Articaine HCl/ 1:100,000 Epinephrine		2X Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: BLACK</b>				
<b>Total Number of Cartridges Received</b>				
N	4	2		
MEAN	1.0	2.0		
SEM	0.00	0.00		
MEDIAN	1.0	2.0		
MIN				
MAX				
MISSING	0	0		
<b>Dose (.ng/kg)</b>				
N	4	2		
MEAN	2.66	5.37		
SEM	0.454	2.114		
MEDIAN	2.65	5.37		
MIN				
MAX				
MISSING	0	0		

Table 2.1.3  
 Summary of Study Drug Administration by Stratification, Age Group and Race  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: ASIAN</b>				
Number of Subjects	2		1	
<b>Duration of Procedure (minutes)</b>				
N	2		1	
MEAN	14.0		2.0	
SEM	1.00			
MEDIAN	14.0		2.0	
MIN				
MAX				
MISSING	0		0	
<b>Calculated Total Volume Received (mL)</b>				
N	2		1	
MEAN	1.7		1.7	
SEM	0.00			
MEDIAN	1.7		1.7	
MIN				
MAX				
MISSING	0		0	

Table 2.1.3  
 Summary of Study Drug Administration by Stratification, Age Group and Race  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Age Group: 4 to <13

	4X Articaine HCl/ 1:100,000 Epinephrine		2X Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: ASIAN</b>				
<b>Total Number of Cartridges Received</b>				
N	2		1	
MEAN	1.0		1.0	
SEM	0.00			
MEDIAN	1.0		1.0	
MIN				
MAX				
MISSING	0		0	
<b>Dose (mg/kg)</b>				
N	2		1	
MEAN	3.28		1.48	
SEM	0.974			
MEDIAN	3.28		1.48	
MIN				
MAX				
MISSING	0		0	

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4X Articaine HCl/ 1:100,000 Epinephrine		2X Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: HISPANIC</b>				
Number of Subjects	28	4	13	1
Duration of Procedure (minutes)				
N	28	4	13	1
MEAN	18.7	72.3	22.5	112.0
SEM	3.27	33.31	6.98	
MEDIAN	10.5	73.5	9.0	112.0
MIN				
MAX				
MISSING	0	0	0	0
Calculated Total Volume Received (mL)				
N	28	4	13	1
MEAN	1.9	2.6	1.9	2.6
SEM	0.15	0.49	0.27	
MEDIAN	1.7	2.6	1.7	2.6
MIN				
MAX				
MISSING	0	0	0	0



Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: HISPANIC</b>				
<b>Total Number of Cartridges Received</b>				
N	28	4	13	1
MEAN	1.1	1.5	1.1	1.5
SEM	0.09	0.29	0.16	
MEDIAN	1.0	1.5	1.0	1.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	28	4	13	1
MEAN	2.20	2.32	1.30	1.73
SEM	0.217	1.076	0.166	
MEDIAN	1.83	1.64	1.15	1.73
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: WHITE</b>				
Number of Subjects	447	141	233	68
<b>Duration of Procedure (minutes)</b>				
N	447	141	231	68
MEAN	39.2	54.4	39.6	48.5
SEM	1.70	3.56	2.55	4.69
MEDIAN	30.0	44.0	32.0	39.0
MIN				
MAX				
MISSING	0	0	2	0
<b>Calculated Total Volume Received (mL)</b>				
N	447	141	233	67
MEAN	2.5	4.3	2.6	4.6
SEM	0.09	0.18	0.11	0.26
MEDIAN	1.7	3.4	1.7	4.3
MIN				
MAX				
MISSING	0	0	0	1

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: WHITE</b>				
<b>Total Number of Cartridges Received</b>				
N	447	141	233	67
MEAN	1.5	2.5	1.5	2.7
SEM	0.05	0.11	0.06	0.15
MEDIAN	1.0	2.0	1.0	2.5
MIN				
MAX				
MISSING	0	0	0	1
<b>Dose (mg/kg)</b>				
N	444	141	229	67
MEAN	1.41	2.36	0.75	1.28
SEM	0.050	0.110	0.031	0.083
MEDIAN	1.05	2.06	0.58	1.20
MIN				
MAX				
MISSING	3	0	4	1

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: BLACK</b>				
Number of Subjects	47	18	21	11
<b>Duration of Procedure (minutes)</b>				
N	47	18	21	11
MEAN	47.9	72.7	40.4	78.9
SEM	4.66	14.14	9.20	15.06
MEDIAN	42.0	60.0	32.0	93.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Calculated Total Volume Received (ml.)</b>				
N	47	18	21	11
MEAN	3.0	5.3	3.8	4.6
SEM	0.31	0.56	0.59	0.95
MEDIAN	2.6	5.1	3.4	3.4
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: BLACK</b>				
<b>Total Number of Cartridges Received</b>				
N	47	18	21	11
MEAN	1.7	3.1	2.2	2.7
SEM	0.18	0.33	0.35	0.56
MEDIAN	1.5	3.0	2.0	2.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	47	18	21	11
MEAN	1.56	2.84	1.02	1.19
SEM	0.142	0.387	0.210	0.219
MEDIAN	1.36	2.66	0.82	0.95
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: ASIAN</b>				
Number of Subjects	35	6	20	6
<b>Duration of Procedure (minutes)</b>				
N	34	6	20	6
MEAN	35.4	40.7	49.3	61.8
SEM	5.46	7.70	7.09	19.64
MEDIAN	28.5	43.0	48.0	61.5
MIN				
MAX				
MISSING	1	0	0	0
<b>Calculated Total Volume Received (mL)</b>				
N	35	6	20	6
MEAN	2.0	4.9	2.5	5.5
SEM	0.23	1.04	0.43	0.44
MEDIAN	1.7	4.9	1.7	5.5
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: ASIAN</b>				
<b>Total Number of Cartridges Received</b>				
N	35	6	20	6
MEAN	1.2	2.9	1.5	3.2
SEM	0.13	0.61	0.25	0.26
MEDIAN	1.0	2.9	1.0	3.3
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	35	6	20	6
MEAN	1.25	3.12	0.86	1.99
SEM	0.148	0.680	0.171	0.186
MEDIAN	1.05	2.61	0.62	1.95
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: HISPANIC</b>				
Number of Subjects	47	14	20	7
<b>Duration of Procedure (minutes)</b>				
N	47	14	20	7
MEAN	27.6	61.0	19.0	32.7
SEM	2.88	9.86	3.07	11.41
MEDIAN	21.0	57.5	14.0	35.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Calculated Total Volume Received (mL)</b>				
N	47	14	20	7
MEAN	2.6	3.3	2.2	3.9
SEM	0.22	0.45	0.28	0.81
MEDIAN	1.7	3.4	1.7	3.4
MIN				
MAX				
MISSING	0	0	0	0



Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: HISPANIC</b>				
<b>Total Number of Cartridges Received</b>				
N	47	14	20	7
MEAN	1.5	2.0	1.3	2.3
SEM	0.13	0.27	0.16	0.47
MEDIAN	1.0	2.0	1.0	2.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	47	14	20	7
MEAN	1.71	1.74	0.65	1.08
SEM	0.185	0.196	0.087	0.245
MEDIAN	1.17	1.81	0.51	1.07
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: OTHER</b>				
Number of Subjects	21	2	7	3
<b>Duration of Procedure (minutes)</b>				
N	21	2	7	3
MEAN	34.6	135.0	50.7	52.7
SEM	4.77	25.00	12.40	20.04
MEDIAN	38.0	135.0	59.0	57.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Calculated Total Volume Received (mL)</b>				
N	21	2	7	3
MEAN	1.9	2.6	1.9	3.7
SEM	0.19	0.85	0.24	1.02
MEDIAN	1.7	2.6	1.7	4.3
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: OTHER</b>				
<b>Total Number of Cartridges Received</b>				
N	21	2	7	3
MEAN	1.1	1.5	1.1	2.2
SEM	0.11	0.50	0.14	0.60
MEDIAN	1.0	1.5	1.0	2.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	21	2	7	3
MEAN	1.23	1.63	0.65	1.01
SEM	0.118	0.267	0.066	0.267
MEDIAN	1.11	1.63	0.57	1.18
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: WHITE</b>				
Number of Subjects	26	13	16	5
<b>Duration of Procedure (minutes)</b>				
N	26	13	16	4
MEAN	27.8	56.1	26.3	60.8
SEM	4.93	7.07	5.23	12.64
MEDIAN	24.5	53.0	20.0	64.5
MIN				
MAX				
MISSING	0	0	0	1
<b>Calculated Total Volume Received (mL)</b>				
N	26	13	16	5
MEAN	2.0	3.9	2.5	3.7
SEM	0.22	0.50	0.35	0.95
MEDIAN	1.7	3.4	1.7	4.3
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: WHITE</b>				
<b>Total Number of Cartridges Received</b>				
N	26	13	16	5
MEAN	1.2	2.3	1.5	2.2
SEM	0.13	0.29	0.20	0.56
MEDIAN	1.0	2.0	1.0	2.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	26	13	15	5
MEAN	1.11	2.03	0.76	0.88
SEM	0.139	0.246	0.141	0.181
MEDIAN	0.89	1.81	0.50	0.83
MIN				
MAX				
MISSING	0	0	1	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: BLACK</b>				
Number of Subjects	1	1	1	
<b>Duration of Procedure (minutes)</b>				
N	1	1	1	
MEAN	69.0	65.0	15.0	
SEM				
MEDIAN	69.0	65.0	15.0	
MIN				
MAX				
MISSING	0	0	0	
<b>Calculated Total Volume Received (mL)</b>				
N	1	1	1	
MEAN	3.0	3.4	3.0	
SEM				
MEDIAN	3.0	3.4	3.0	
MIN				
MAX				
MISSING	0	0	0	

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: BLACK</b>				
<b>Total Number of Cartridges Received</b>				
N	1	1	1	
MEAN	1.8	2.0	1.8	
SEM				
MEDIAN	1.8	2.0	1.8	
MIN				
MAX				
MISSING	0	0	0	
<b>Dose (mg/kg)</b>				
N	1	1	1	
MEAN	1.27	1.93	0.66	
SEM				
MEDIAN	1.27	1.93	0.66	
MIN				
MAX				
MISSING	0	0	0	

Table 2.1.3  
 Summary of Study Drug Administration by Stratification, Age Group and Race  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Age Group: 65 to <75

	4X Articaine HCl/ 1:100,000 Epinephrine		2X Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: ASIAN</b>				
Number of Subjects		1		
<b>Duration of Procedure (minutes)</b>				
N		1		
MEAN		57.0		
SEM				
MEDIAN		57.0		
MIN				
MAX				
MISSING		0		
<b>Calculated Total Volume Received (mL)</b>				
N		1		
MEAN		3.4		
SEM				
MEDIAN		3.4		
MIN				
MAX				
MISSING		0		



Table 2.1.3  
 Summary of Study Drug Administration by Stratification, Age Group and Race  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: ASIAN</b>				
<b>Total Number of Cartridges Received</b>				
N		1		
MEAN		2.0		
SEM				
MEDIAN		2.0		
MIN		—		
MAX		—		
MISSING		0		
<b>Dose (mg/kg)</b>				
N		1		
MEAN		2.23		
SEM				
MEDIAN		2.23		
MIN		—		
MAX		—		
MISSING		0		

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: HISPANIC</b>				
Number of Subjects	1		1	
<b>Duration of Procedure (minutes)</b>				
N	1		1	
MEAN	10.0		32.0	
SEM				
MEDIAN	10.0		32.0	
MIN				
MAX				
MISSING	0		0	
<b>Calculated Total Volume Received (mL)</b>				
N	1		1	
MEAN	1.7		10.2	
SEM				
MEDIAN	1.7		10.2	
MIN				
MAX				
MISSING	0		0	

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: HISPANIC</b>				
<b>Total Number of Cartridges Received</b>				
N	1		1	
MEAN	1.0		6.0	
SEM				
MEDIAN	1.0		6.0	
MIN				
MAX				
MISSING	0		0	
<b>Dose (mg/kg)</b>				
N	1		1	
MEAN	0.86		2.43	
SEM				
MEDIAN	0.86		2.43	
MIN				
MAX				
MISSING	0		0	

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: WHITE</b>				
Number of Subjects	6	4	1	2
<b>Duration of Procedure (minutes)</b>				
N	6	4	1	2
MEAN	12.7	98.0	139.0	78.0
SEM	3.59	39.70		42.00
MEDIAN	10.0	64.5	139.0	78.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Calculated Total Volume Received (mL)</b>				
N	6	4	1	2
MEAN	3.3	3.5	1.7	4.7
SEM	1.72	0.82		0.42
MEDIAN	1.7	3.8	1.7	4.7
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: WHITE</b>				
<b>Total Number of Cartridges Received</b>				
N	6	4	1	2
MEAN	2.0	2.1	1.0	2.8
SEM	1.01	0.48		0.25
MEDIAN	1.0	2.3	1.0	2.8
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	6	4	1	2
MEAN	1.57	1.86	0.34	1.19
SEM	0.640	0.248		0.168
MEDIAN	0.94	2.08	0.34	1.19
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: BLACK</b>				
Number of Subjects	1			1
<b>Duration of Procedure (minutes)</b>				
N	1			1
MEAN	18.0			28.0
SEM				
MEDIAN	18.0			28.0
MIN				
MAX				
MISSING	0			0
<b>Calculated Total Volume Received (mL)</b>				
N	1			1
MEAN	5.1			1.7
SEM				
MEDIAN	5.1			1.7
MIN				
MAX				
MISSING	0			0

Table 2.1.3  
Summary of Study Drug Administration by Stratification, Age Group and Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Race: BLACK</b>				
<b>Total Number of Cartridges Received</b>				
N	1			1
MEAN	3.0			1.0
SEM				
MEDIAN	3.0			1.0
MIN				
MAX				
MISSING	0			0
<b>Dose (mg/kg)</b>				
N	1			1
MEAN	2.99			0.43
SEM				
MEDIAN	2.99			0.43
MIN				
MAX				
MISSING	0			0

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: FEMALE</b>				
Number of Subjects	19	2	12	1
<b>Duration of Procedure (minutes)</b>				
N	19	2	12	1
MEAN	19.9	67.0	16.1	112.0
SEM	4.58	37.00	5.99	
MEDIAN	11.0	67.0	8.0	112.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Calculated Total Volume Received (mL)</b>				
N	19	2	12	1
MEAN	1.9	2.6	1.7	2.6
SEM	0.16	0.85	0.20	
MEDIAN	1.7	2.6	1.7	2.6
MIN				
MAX				
MISSING	0	0	0	0



Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: FEMALE</b>				
<b>Total Number of Cartridges Received</b>				
N	19	2	12	1
MEAN	1.1	1.5	1.0	1.5
SEM	0.09	0.50	0.12	
MEDIAN	1.0	1.5	1.0	1.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	19	2	12	1
MEAN	2.54	2.07	1.22	1.73
SEM	0.323	1.186	0.148	
MEDIAN	2.30	2.07	1.15	1.73
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: MALE</b>				
Number of Subjects	24	5	6	1
<b>Duration of Procedure (minutes)</b>				
N	24	5	6	1
MEAN	12.7	70.2	25.8	1.0
SEM	2.41	26.49	10.21	
MEDIAN	8.5	70.0	16.5	1.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Calculated Total Volume Received (mL)</b>				
N	24	5	6	1
MEAN	1.9	2.5	2.2	2.6
SEM	0.14	0.56	0.55	
MEDIAN	1.7	3.4	2.6	2.6
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: MALE</b>				
<b>Total Number of Cartridges Received</b>				
N	24	5	6	1
MEAN	1.1	1.5	1.3	1.5
SEM	0.08	0.33	0.32	
MEDIAN	1.0	2.0	1.5	1.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	24	5	6	1
MEAN	2.23	3.25	1.39	1.13
SEM	0.205	1.377	0.334	
MEDIAN	1.87	2.39	1.64	1.13
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: FEMALE</b>				
Number of Subjects	319	94	183	49
<b>Duration of Procedure (minutes)</b>				
N	319	94	183	49
MEAN	39.1	61.8	35.7	62.0
SEM	1.87	4.51	2.49	6.42
MEDIAN	32.0	53.5	30.0	50.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Calculated Total Volume Received (mL)</b>				
N	319	94	183	48
MEAN	2.5	4.2	2.6	4.7
SEM	0.10	0.21	0.12	0.31
MEDIAN	1.7	3.4	1.7	4.3
MIN				
MAX				
MISSING	0	0	0	1

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: FEMALE</b>				
<b>Total Number of Cartridges Received</b>				
N	319	94	183	48
MEAN	1.4	2.5	1.5	2.8
SEM	0.06	0.12	0.07	0.18
MEDIAN	1.0	2.0	1.0	2.5
MIN				
MAX				
MISSING	0	0	0	1
<b>Dose (mg/kg)</b>				
N	317	94	180	48
MEAN	1.54	2.55	0.82	1.44
SEM	0.065	0.136	0.039	0.106
MEDIAN	1.18	2.27	0.61	1.28
MIN				
MAX				
MISSING	2	0	3	1

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: MALE</b>				
Number of Subjects	278	87	118	46
<b>Duration of Procedure (minutes)</b>				
N	277	87	116	46
MEAN	38.0	52.2	44.7	41.0
SEM	2.11	4.76	3.96	4.88
MEDIAN	29.0	42.0	35.0	33.0
MIN				
MAX				
MISSING	1	0	2	0
<b>Calculated Total Volume Received (mL)</b>				
N	278	87	118	46
MEAN	2.6	4.4	2.7	4.4
SEM	0.11	0.26	0.18	0.33
MEDIAN	1.7	4.1	1.7	4.3
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.4  
 Summary of Study Drug Administration by Stratification, Age Group and Gender  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: MALE</b>				
<b>Total Number of Cartridges Received</b>				
N	278	87	118	46
MEAN	1.5	2.6	1.6	2.6
SEM	0.07	0.15	0.10	0.19
MEDIAN	1.0	2.4	1.0	2.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	277	87	117	46
MEAN	1.30	2.20	0.69	1.14
SEM	0.054	0.142	0.052	0.087
MEDIAN	0.96	1.87	0.52	1.08
MIN				
MAX				
MISSING	1	0	1	0

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: FEMALE</b>				
Number of Subjects	16	9	11	2
<b>Duration of Procedure (minutes)</b>				
N	16	9	11	1
MEAN	24.2	55.8	23.3	55.0
SEM	4.27	7.88	5.86	
MEDIAN	24.5	57.0	16.0	55.0
MIN				
MAX				
MISSING	0	0	0	1
<b>Calculated Total Volume Received (mL)</b>				
N	16	9	11	2
MEAN	2.1	3.5	3.1	4.3
SEM	0.26	0.64	0.40	2.55
MEDIAN	1.7	3.4	3.4	4.3
MIN				
MAX				
MISSING	0	0	0	0



Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: FEMALE</b>				
<b>Total Number of Cartridges Received</b>				
N	16	9	11	2
MEAN	1.2	2.1	1.8	2.5
SEM	0.15	0.37	0.23	1.50
MEDIAN	1.0	2.0	2.0	2.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	16	9	10	2
MEAN	1.25	2.08	1.00	1.06
SEM	0.201	0.345	0.166	0.431
MEDIAN	0.91	1.93	1.02	1.06
MIN				
MAX				
MISSING	0	0	1	0

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: MALE</b>				
Number of Subjects	12	6	7	3
<b>Duration of Procedure (minutes)</b>				
N	12	6	7	3
MEAN	34.5	58.2	30.1	62.7
SEM	9.80	10.61	8.08	17.68
MEDIAN	27.5	62.5	25.0	74.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Calculated Total Volume Received (mL)</b>				
N	12	6	7	3
MEAN	1.9	4.3	2.7	3.4
SEM	0.34	0.50	1.26	0.85
MEDIAN	1.7	3.6	1.7	4.3
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: MALE</b>				
<b>Total Number of Cartridges Received</b>				
N	12	6	7	3
MEAN	1.1	2.5	1.6	2.0
SEM	0.20	0.30	0.74	0.50
MEDIAN	1.0	2.1	1.0	2.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	12	6	7	3
MEAN	0.91	1.99	0.66	0.76
SEM	0.127	0.170	0.301	0.172
MEDIAN	0.80	1.90	0.36	0.83
MIN				
MAX				
MISSING	0	0	0	0

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: FEMALE</b>				
Number of Subjects	2	3	1	
<b>Duration of Procedure (minutes)</b>				
N	2	3	1	
MEAN	13.5	104.0	139.0	
SEM	4.50	55.50		
MEDIAN	13.5	49.0	139.0	
MIN				
MAX				
MISSING	0	0	0	
<b>Calculated Total Volume Received (mL)</b>				
N	2	3	1	
MEAN	3.4	3.0	1.7	
SEM	1.70	0.88		
MEDIAN	3.4	3.4	1.7	
MIN				
MAX				
MISSING	0	0	0	

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: FEMALE</b>				
<b>Total Number of Cartridges Received</b>				
N	2	3	1	
MEAN	2.0	1.8	1.0	
SEM	1.00	0.52		
MEDIAN	2.0	2.0	1.0	
MIN				
MAX				
MISSING	0	0	0	
<b>Dose (mg/kg)</b>				
N	2	3	1	
MEAN	2.07	1.79	0.34	
SEM	0.921	0.334		
MEDIAN	2.07	2.06	0.34	
MIN				
MAX				
MISSING	0	0	0	

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: MALE</b>				
Number of Subjects	5	1		3
<b>Duration of Procedure (minutes)</b>				
N	5	1		3
MEAN	13.4	80.0		61.3
SEM	4.31			29.42
MEDIAN	10.0	80.0		36.0
MIN				
MAX				
MISSING	0	0		0
<b>Calculated Total Volume Received (mL)</b>				
N	5	1		3
MEAN	3.7	5.1		3.7
SEM	2.06			1.02
MEDIAN	1.7	5.1		4.3
MIN				
MAX				
MISSING	0	0		0

Table 2.1.4  
Summary of Study Drug Administration by Stratification, Age Group and Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Gender: MALE</b>				
<b>Total Number of Cartridges Received</b>				
N	5	1		3
MEAN	2.2	3.0		2.2
SEM	1.21			0.60
MEDIAN	1.0	3.0		2.5
MIN				
MAX				
MISSING	0	0		0
<b>Dose (mg/kg)</b>				
N	5	1		3
MEAN	1.65	2.09		0.93
SEM	0.778			0.271
MEDIAN	0.91	2.09		1.02
MIN				
MAX				
MISSING	0	0		0

Table 2.2.1  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02 and S96002.01  
All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Number of Subjects</b>	41	6	17	1
<b>Duration of Procedure (minutes)</b>				
N	41	6	17	1
MEAN	16.3	77.2	20.4	112.0
SEM	2.56	21.74	5.40	
MEDIAN	9.0	87.0	9.0	112.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Calculated Total Volume Received (mL)</b>				
N	41	6	17	1
MEAN	1.9	2.8	1.9	2.6
SEM	0.11	0.36	0.24	
MEDIAN	1.7	3.4	1.7	2.6
MIN				
MAX				
MISSING	0	0	0	0



Table 2.2.1  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02 and S96002.01  
All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	41	6	17	1
MEAN	1.1	1.7	1.1	1.5
SEM	0.06	0.21	0.14	
MEDIAN	1.0	2.0	1.0	1.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	41	6	17	1
MEAN	2.32	3.34	1.26	1.73
SEM	0.185	1.083	0.152	
MEDIAN	1.87	2.82	1.15	1.73
MIN				
MAX				
MISSING	0	0	0	0

Table 2.2.1  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02 and S96002.01  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Number of Subjects</b>	491	139	244	72
<b>Duration of Procedure (minutes)</b>				
N	491	139	243	72
MEAN	43.6	68.5	44.7	61.8
SEM	1.57	3.71	2.50	4.83
MEDIAN	35.0	56.0	35.0	51.5
MIN				
MAX				
MISSING	0	0	1	0
<b>Calculated Total Volume Received (mL)</b>				
N	491	139	244	71
MEAN	2.6	4.3	2.7	4.5
SEM	0.08	0.17	0.12	0.25
MEDIAN	1.7	3.4	1.7	4.3
MIN				
MAX				
MISSING	0	0	0	1

Table 2.2.1  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02 and S96002.01  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	491	139	244	71
MEAN	1.5	2.5	1.6	2.7
SEM	0.05	0.10	0.07	0.15
MEDIAN	1.0	2.0	1.0	2.5
MIN				
MAX				
MISSING	0	0	0	1
<b>Dose (mg/kg)</b>				
N	488	139	240	71
MEAN	1.45	2.34	0.78	1.25
SEM	0.049	0.106	0.037	0.077
MEDIAN	1.08	2.02	0.58	1.16
MIN				
MAX				
MISSING	3	0	4	1

Table 2.2.1  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02 and S96002.01  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
Number of Subjects	22	15	16	5
Duration of Procedure (minutes)				
N	22	15	16	4
MEAN	34.4	56.7	27.6	60.8
SEM	5.49	6.12	5.12	12.64
MEDIAN	30.5	57.0	23.5	64.5
MIN				
MAX				
MISSING	0	0	0	1
Calculated Total Volume Received (mL)				
N	22	15	16	5
MEAN	1.8	3.8	2.9	3.7
SEM	0.21	0.43	0.56	0.95
MEDIAN	1.7	3.4	2.1	4.3
MIN				
MAX				
MISSING	0	0	0	0

Table 2.2.1  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02 and S96002.01  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	22	15	16	5
MEAN	1.0	2.2	1.7	2.2
SEM	0.12	0.25	0.33	0.56
MEDIAN	1.0	2.0	1.3	2.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	22	15	15	5
MEAN	0.91	2.04	0.84	0.88
SEM	0.111	0.212	0.167	0.181
MEDIAN	0.79	1.93	0.51	0.83
MIN				
MAX				
MISSING	0	0	1	0

Table 2.2.1  
Summary of Study Drug Administration by Stratification and Age Group  
Protocols S96001.02 and S96002.01  
All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Number of Subjects</b>	6	4	1	3
<b>Duration of Procedure (minutes)</b>				
N	6	4	1	3
MEAN	14.8	98.0	139.0	61.3
SEM	3.31	39.70		29.42
MEDIAN	11.0	64.5	139.0	36.0
MIN				
MAX				
MISSING	0	0	0	0
<b>Calculated Total Volume Received (mL)</b>				
N	6	4	1	3
MEAN	4.0	3.5	1.7	3.7
SEM	1.68	0.82		1.02
MEDIAN	1.7	3.8	1.7	4.3
MIN				
MAX				
MISSING	0	0	0	0

Table 2.2.1  
 Summary of Study Drug Administration by Stratification and Age Group  
 Protocols S96001.02 and S96002.01  
 All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	6	4	1	3
MEAN	2.3	2.1	1.0	2.2
SEM	0.99	0.48		0.60
MEDIAN	1.0	2.3	1.0	2.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	6	4	1	3
MEAN	1.94	1.86	0.34	0.93
SEM	0.656	0.248		0.271
MEDIAN	1.06	2.08	0.34	1.02
MIN				
MAX				
MISSING	0	0	0	0

Table 2.3.1  
Summary of Study Drug Administration by Stratification and Age Group  
Protocol S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
Number of Subjects	2	1	1	1
Duration of Procedure (minutes)				
N	2	1	1	1
MEAN	8.0	22.0	2.0	1.0
SEM	7.00			
MEDIAN	8.0	22.0	2.0	1.0
MIN				
MAX				
MISSING	0	0	0	0
Calculated Total Volume Received (mL)				
N	2	1	1	1
MEAN	1.7	0.7	1.7	2.6
SEM	0.00			
MEDIAN	1.7	0.7	1.7	2.6
MIN				
MAX				
MISSING	0	0	0	0



Table 2.3.1  
 Summary of Study Drug Administration by Stratification and Age Group  
 Protocol S96001.02UK  
 All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	2	1	1	1
MEAN	1.0	0.4	1.0	1.5
SEM	0.00			
MEDIAN	1.0	0.4	1.0	1.5
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	2	1	1	1
MEAN	3.49	0.37	1.48	1.13
SEM	0.765			
MEDIAN	3.49	0.37	1.48	1.13
MIN				
MAX				
MISSING	0	0	0	0

Table 2.3.1  
Summary of Study Drug Administration by Stratification and Age Group  
Protocol S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Number of Subjects</b>	106	42	57	23
<b>Duration of Procedure (minutes)</b>				
N	105	42	56	23
MEAN	14.9	19.8	14.9	20.6
SEM	1.57	2.53	2.03	3.99
MEDIAN	10.0	14.0	10.0	16.0
MIN				
MAX				
MISSING	1	0	1	0
<b>Calculated Total Volume Received (mL)</b>				
N	106	42	57	23
MEAN	2.4	4.3	2.4	4.7
SEM	0.16	0.42	0.16	0.49
MEDIAN	1.7	3.4	1.7	4.6
MIN				
MAX				
MISSING	0	0	0	0

Table 2.3.1  
Summary of Study Drug Administration by Stratification and Age Group  
Protocol S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	106	42	57	23
MEAN	1.4	2.6	1.4	2.8
SEM	0.09	0.25	0.09	0.29
MEDIAN	1.0	2.0	1.0	2.7
MIN				
MAX				
MISSING	0	0	0	0
<b>Dose (mg/kg)</b>				
N	106	42	57	23
MEAN	1.35	2.51	0.71	1.42
SEM	0.085	0.245	0.050	0.159
MEDIAN	1.07	2.24	0.59	1.29
MIN				
MAX				
MISSING	0	0	0	0

Table 2.3.1  
Summary of Study Drug Administration by Stratification and Age Group  
Protocol S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4X Articaine HCl/ 1:100,000 Epinephrine		2X Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Number of Subjects</b>	6		2	
<b>Duration of Procedure (minutes)</b>				
N	6		2	
MEAN	7.3		12.5	
SEM	3.57		3.50	
MEDIAN	3.0		12.5	
MIN				
MAX				
MISSING	0		0	
<b>Calculated total Volume Received (mL)</b>				
N	6		2	
MEAN	3.0		3.0	
SEM	0.43		2.12	
MEDIAN	3.4		3.0	
MIN				
MAX				
MISSING	0		0	

Table 2.3.1  
Summary of Study Drug Administration by Stratification and Age Group  
Protocol S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	6		2	
MEAN	1.8		1.8	
SEM	0.25		1.25	
MEDIAN	2.0		1.8	
MIN				
MAX				
MISSING	0		0	
<b>Dose (mg/kg)</b>				
N	6		2	
MEAN	1.81		0.94	
SEM	0.322		0.701	
MEDIAN	1.67		0.94	
MIN				
MAX				
MISSING	0		0	

Table 2.3.1  
 Summary of Study Drug Administration by Stratification and Age Group  
 Protocol S96001.02UK  
 All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
Number of Subjects	1			
Duration of Procedure (minutes)				
N	1			
MEAN	5.0			
SEM				
MEDIAN	5.0			
MIN	—			
MAX				
MISSING	0			
Calculated Total Volume Received (mL)				
N	1			
MEAN	1.3			
SEM				
MEDIAN	1.3			
MIN	—			
MAX				
MISSING	0			

Table 2.3.1  
 Summary of Study Drug Administration by Stratification and Age Group  
 Protocol S96001.02UK  
 All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine		2% Lidocaine HCl/ 1:100,000 Epinephrine	
	Simple	Complex	Simple	Complex
<b>Total Number of Cartridges Received</b>				
N	1			
MEAN	0.8			
SEM				
MEDIAN	0.8			
MIN				
MAX				
MISSING	0			
<b>Dose (mg/kg)</b>				
N	1			
MEAN	0.78			
SEM				
MEDIAN	0.78			
MIN				
MAX				
MISSING	0			

Table 2.4.1  
Summary of Study Drug Administration by Dose  
Protocol S97001  
All Treated Patients

---

	4% Articaine HCl/ 1:200,000 Epinephrine	
	Single	Multiple
Number of Subjects	20	20
Calculated Total Volume Received (mL)		
MEAN	1.70	5.10
SEM	0.000	0.000
MEDIAN	1.7	5.1
MIN		
MAX		

---



Table 2.4.2  
Summary of Study Drug Administration by Dose and Age Group  
Protocol S97001  
All Treated Patients

Age Group: 13 to <65

---

	4% Articaine HCl/ 1:200,000 Epinephrine	
	Single	Multiple
Number of Subjects	20	20
Calculated Total Volume Received (mL)		
MEAN	1.70	5.10
SEM	0.000	0.000
MEDIAN	1.7	5.1
MIN		
MAX		

---

Table 2.4.3  
Summary of Study Drug Administration by Dose and Race  
Protocol S97001  
All Treated Patients

Race: WHITE

---

	4% Articaine HCl/ 1:200,000 Epinephrine	
	Single	Multiple
Number of Subjects	5	5
Calculated Total Volume Received (mL)		
MEAN	1.70	5.10
SEM	0.000	0.000
MEDIAN	1.7	5.1
MIN		
MAX		

---

Table 2.4.3  
Summary of Study Drug Administration by Dose and Race  
Protocol S97001  
All Treated Patients

Race: BLACK

---

	4% Articaine HCl/ 1:200,000 Epinephrine	
	Single	Multiple
Number of Subjects	3	3
Calculated Total Volume Received (mL)		
MEAN	1.70	5.10
SEM	0.000	0.000
MEDIAN	1.7	5.1
MIN		
MAX		

---

Table 2.4.3  
Summary of Study Drug Administration by Dose and Race  
Protocol S97001  
All Treated Patients

Race: HISPANIC

---

	4% Articaine HCl/ 1:200,000 Epinephrine	
	Single	Multiple
Number of Subjects	12	12
Calculated Total Volume Received (mL)		
MEAN	1.70	5.10
SEM	0.000	0.000
MEDIAN	1.7	5.1
MIN		
MAX		

---

Table 2.4.4  
Summary of Study Drug Administration by Dose and Gender  
Protocol S97001  
All Treated Patients

Gender: FEMALE

---

	4% Articaine HCl/ 1:200,000 Epinephrine	
	Single	Multiple
Number of Subjects	10	10
Calculated Total Volume Received (mL)		
MEAN	1.70	5.10
SEM	0.000	0.000
MEDIAN	1.7	5.1
MIN		
MAX		

---

Table 2.4.4  
Summary of Study Drug Administration by Dose and Gender  
Protocol S97001  
All Treated Patients

Gender: MALE

---

	4X Articaine HCl/ 1:200,000 Epinephrine	
	Single	Multiple
Number of Subjects	10	10
Calculated Total Volume Received (mL)		
MEAN	1.70	5.10
SEM	0.000	0.000
MEDIAN	1.7	5.1
MIN		
MAX		

---

Table 3.1.1  
Summary of Patient Disposition  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	883	443	1326
Randomized, Not Treated	1	0	1
All Treated Patients	882	443	1325
Completed Study (CRF Checkbox)	862 ( 98%)	425 ( 96%)	1287 ( 97%)
Discontinued Patients			
Discontinued due to adverse event	0	1 ( <1%)	1 ( <1%)
Protocol deviation	18 ( 2%)	12 ( 3%)	30 ( 2%)
Patient lost to follow-up	1 ( <1%)	5 ( 1%)	6 ( <1%)
Other	1 ( <1%)	0	1 ( <1%)

Percents are based on the number of treated patients in each treatment group.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.1.2  
Summary of Patient Disposition by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 4 to <13

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	50	20	70
All Treated Patients	50	20	70
Completed Study (CRF Checkbox)	50 (100%)	20 (100%)	70 (100%)

Percents are based on the number of treated patients in each treatment group.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.



Table 3.1.2  
Summary of Patient Disposition by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 13 to <65

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	778	396	1174
All Treated Patients	778	396	1174
Completed Study (CRF Checkbox)	758 ( 97%)	379 ( 96%)	1137 ( 97%)
Discontinued Patients			
Protocol deviation	18 ( 2%)	12 ( 3%)	30 ( 3%)
Patient lost to follow-up	1 ( <1%)	5 ( 1%)	6 ( 1%)
Other	1 ( <1%)	0	1 ( <1%)

Percents are based on the number of treated patients in each treatment group.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.1.2  
Summary of Patient Disposition by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: 65 to <75

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	44	23	67
Randomized, Not Treated	1	0	1
All Treated Patients	43	23	66
Completed Study (CRF Checkbox)	43 (100%)	22 ( 96%)	65 ( 98%)
Discontinued Patients Discontinued due to adverse event	0	1 ( 4%)	1 ( 2%)

Percents are based on the number of treated patients in each treatment group.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.1.2  
Summary of Patient Disposition by Age Group  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Age Group: >=75

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	11	4	15
All Treated Patients	11	4	15
Completed Study (CRF Checkbox)	11 (100%)	4 (100%)	15 (100%)

Percents are based on the number of treated patients in each treatment group.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.1.3  
 Summary of Patient Disposition by Race  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

Race: WHITE

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	648	330	978
Randomized, Not Treated	1	0	1
All Treated Patients	647	330	977
Completed Study (CRF Checkbox)	629 ( 97%)	312 ( 95%)	941 ( 96%)
Discontinued Patients			
Discontinued due to adverse event	0	1 ( <1%)	1 ( <1%)
Protocol deviation	16 ( 2%)	12 ( 4%)	28 ( 3%)
Patient lost to follow-up	1 ( <1%)	5 ( 2%)	6 ( 1%)
Other	1 ( <1%)	0	1 ( <1%)

Percents are based on the number of treated patients in each treatment group.  
 Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.1.3  
Summary of Patient Disposition by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: BLACK

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	74	34	108
All Treated Patients	74	34	108
Completed Study (CRF Checkbox)	74 (100%)	34 (100%)	108 (100%)

Percents are based on the number of treated patients in each treatment group.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.1.3  
Summary of Patient Disposition by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: ASIAN

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	44	27	71
All Treated Patients	44	27	71
Completed Study (CRF Checkbox)	43 ( 98%)	27 (100%)	70 ( 99%)
Discontinued Patients Protocol deviation	1 ( 2%)	0	1 ( 1%)

Percents are based on the number of treated patients in each treatment group.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.1.3  
Summary of Patient Disposition by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: HISPANIC

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	94	42	136
All Treated Patients	94	42	136
Completed Study (CRF Checkbox)	94 (100%)	42 (100%)	136 (100%)

Percents are based on the number of treated patients in each treatment group.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.1.3  
Summary of Patient Disposition by Race  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Race: OTHER

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	23	10	33
All Treated Patients	23	10	33
Completed Study (CRF Checkbox)	22 ( 96%)	10 (100%)	32 ( 97%)
Discontinued Patients Protocol deviation	1 ( 4%)	0	1 ( 3%)

Percents are based on the number of treated patients in each treatment group.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.



Table 3.1.4  
Summary of Patient Disposition by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: FEMALE

	4X Articaine HCl/ 1:100,000 Epinephrine	2X Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	464	259	723
All Treated Patients	464	259	723
Completed Study (CRF Checkbox)	456 ( 98%)	249 ( 96%)	705 ( 98%)
Discontinued Patients			
Discontinued due to adverse event	0	1 ( <1%)	1 ( <1%)
Protocol deviation	7 ( 2%)	8 ( 3%)	15 ( 2%)
Patient lost to follow-up	1 ( <1%)	1 ( <1%)	2 ( <1%)

Percents are based on the number of treated patients in each treatment group.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.1.4  
Summary of Patient Disposition by Gender  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

Gender: MALE

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	419	184	603
Randomized, Not Treated	1	0	1
All Treated Patients	418	184	602
Completed Study (CRF Checkbox)	406 ( 97%)	176 ( 96%)	582 ( 97%)
Discontinued Patients			
Protocol deviation	11 ( 3%)	4 ( 2%)	15 ( 2%)
Patient lost to follow-up	0	4 ( 2%)	4 ( 1%)
Other	1 ( <1%)	0	1 ( <1%)

Percents are based on the number of treated patients in each treatment group.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.2.1  
 Summary of Patient Disposition  
 Protocols S96001.02 and S96002.01  
 All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	724	359	1083
All Treated Patients	724	359	1083
Completed Study (CRF Checkbox)	723 (>99%)	356 ( 99%)	1079 (>99%)
Discontinued Patients			
Discontinued due to adverse event	0	1 ( <1%)	1 ( <1%)
Protocol deviation	1 ( <1%)	0	1 ( <1%)
Patient lost to follow-up	0	2 ( 1%)	2 ( <1%)

Percents are based on the number of treated patients in each treatment group.  
 Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.3.1  
 Summary of Patient Disposition  
 Protocol S96001.02UK  
 All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine	2% Lidocaine HCl/ 1:100,000 Epinephrine	Total
All Randomized Patients	159	84	243
Randomized, Not Treated	1	0	1
All Treated Patients	158	84	242
Completed Study (CRF Checkbox)	139 ( 88%)	69 ( 82%)	208 ( 86%)
Discontinued Patients			
Protocol deviation	17 ( 11%)	12 ( 14%)	29 ( 12%)
Patient lost to follow-up	1 ( 1%)	3 ( 4%)	4 ( 2%)
Other	1 ( 1%)	0	1 ( <1%)

Percents are based on the number of treated patients in each treatment group.  
 Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.4.1  
Summary of Patient Disposition  
Protocol S97001  
All Treated Patients

---

	4% Articaine HCl/ 1:200,000 Epinephrine
All Treated Patients	20
Completed Study (CRF Checkbox)	20 (100%)

---

Percents are based on the number of treated patients.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.4.2  
Summary of Patient Disposition by Age Group  
Protocol S97001  
All Treated Patients

Age Group: 13 to <65

---

	4% Articaine HCl/ 1:200,000 Epinephrine
All Treated Patients	20
Completed Study (CRF Checkbox)	20 (100%)

---

Percents are based on the number of treated patients.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.4.3  
Summary of Patient Disposition by Race  
Protocol S97001  
All Treated Patients

Race: WHITE

---

	4% Articaine HCl/ 1:200,000 Epinephrine
All Treated Patients	5
Completed Study (CRF Checkbox)	5 (100%)

---

Percents are based on the number of treated patients.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.4.3  
Summary of Patient Disposition by Race  
Protocol S97001  
All Treated Patients

Race: BLACK

---

	4% Articaine HCl/ 1:200,000 Epinephrine
All Treated Patients	3
Completed Study (CRF Checkbox)	3 (100%)

---

Percents are based on the number of treated patients.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.



Table 3.4.3  
Summary of Patient Disposition by Race  
Protocol S97001  
All Treated Patients

Race: HISPANIC

---

	4% Articaine HCl/ 1:200,000 Epinephrine
All Treated Patients	12
Completed Study (CRF Checkbox)	12 (100%)

---

Percents are based on the number of treated patients.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.4.4  
Summary of Patient Disposition by Gender  
Protocol S97001  
All Treated Patients

Gender: FEMALE

---

	4% Articaine HCl/ 1:200,000 Epinephrine
All Treated Patients	10
Completed Study (CRF Checkbox)	10 (100%)

---

Percents are based on the number of treated patients.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 3.4.4  
Summary of Patient Disposition by Gender  
Protocol S97001  
All Treated Patients

Gender: MALE

---

	4% Articaine HCl/ 1:200,000 Epinephrine
All Treated Patients	10
Completed Study (CRF Checkbox)	10 (100%)

---

Percents are based on the number of treated patients.  
Patients may have had multiple reasons for discontinuation. All reasons are summarized, therefore percents may add to more than 100%.

Table 4.1.1  
Summary of Mean Change From Baseline in Vital Signs  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine			2% Lidocaine HCl/ 1:100,000 Epinephrine			P-value
	Baseline	Visit	Change	Baseline	Visit	Change	
<b>Supine Systolic Blood Pressure (mmHg)</b>							
<b>Baseline</b>							
N	882			443			0.514
MEAN	121.0			120.6			
SEM	0.57			0.80			
MEDIAN	120.0			120.0			
MIN MAX							
<b>One Minute Post-therapy</b>							
N	882	882	882	441	441	441	0.182
MEAN	121.0	120.6	-0.4	120.6	120.9	0.3	
SEM	0.57	0.56	0.36	0.80	0.82	0.58	
MEDIAN	120.0	120.0	0.0	120.0	120.0	0.0	
MIN MAX							
<b>Five Minutes Post-therapy</b>							
N	880	880	880	442	442	442	0.179
MEAN	120.9	118.7	-2.2	120.6	119.5	-1.1	
SEM	0.57	0.56	0.40	0.80	0.86	0.63	
MEDIAN	120.0	118.0	-2.0	120.0	118.0	-2.0	
MIN MAX							

The two-sided p-value is from an ANOVA with treatment, age group, center, strata, treatment-by-center interaction and treatment-by-strata interaction effects, comparing treatment groups.

Table 4.1.1  
 Summary of Mean Change From Baseline in Vital Signs  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine			2% Lidocaine HCl/ 1:100,000 Epinephrine			P-value
	Baseline	Visit	Change	Baseline	Visit	Change	
Post Dental Procedure							
N	881	881	881	442	442	442	
MEAN	120.9	120.7	-0.3	120.6	120.7	0.1	0.366
SEM	0.57	0.58	0.41	0.80	0.81	0.57	
MEDIAN	120.0	119.0	0.0	120.0	118.0	0.0	
MIN							
MAX							

The two-sided p-value is from an ANOVA with treatment, age group, center, strata, treatment-by-center interaction and treatment-by-strata interaction effects, comparing treatment groups.

Table 4.1.1  
 Summary of Mean Change From Baseline in Vital Signs  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

	4X Articaine HCl/ 1:100,000 Epinephrine			2X Lidocaine HCl/ 1:100,000 Epinephrine			P-value
	Baseline	Visit	Change	Baseline	Visit	Change	
<b>Supine Diastolic Blood Pressure (mmHg)</b>							
<b>Baseline</b>							
N	882			443			0.411
MEAN	74.3			74.1			
SEM	0.37			0.51			
MEDIAN	74.0			74.0			
MIN							
MAX							
<b>One Minute Post-therapy</b>							
N	882	882	882	441	441	441	0.385
MEAN	74.3	72.8	-1.5	74.1	73.0	-1.1	
SEM	0.37	0.35	0.26	0.51	0.54	0.42	
MEDIAN	74.0	72.0	-1.0	74.0	72.0	-1.0	
MIN							
MAX							
<b>Five Minutes Post-therapy</b>							
N	880	880	880	442	442	442	0.816
MEAN	74.3	70.9	-3.4	74.1	71.0	-3.1	
SEM	0.37	0.37	0.28	0.51	0.53	0.41	
MEDIAN	74.0	70.0	-3.0	74.0	70.0	-2.0	
MIN							
MAX							

The two-sided p-value is from an ANOVA with treatment, age group, center, strata, treatment-by-center interaction and treatment-by-strata interaction effects, comparing treatment groups.

Table 4.1.1  
 Summary of Mean Change From Baseline in Vital Signs  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine			2% Lidocaine HCl/ 1:100,000 Epinephrine			P-value
	Baseline	Visit	Change	Baseline	Visit	Change	
Post Dental Procedure							
N	881	881	881	442	442	442	
MEAN	74.3	73.8	-0.4	74.1	74.5	0.4	0.184
SEM	0.37	0.38	0.30	0.51	0.56	0.45	
MEDIAN	74.0	73.0	0.0	74.0	74.0	0.0	
MIN							
MAX							

The two-sided p-value is from an ANOVA with treatment, age group, center, strata, treatment-by-center interaction and treatment-by-strata interaction effects, comparing treatment groups.

Table 4.1.1  
Summary of Mean Change From Baseline in Vital Signs  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

	4X Articaine HCl/ 1:100,000 Epinephrine			2X Lidocaine HCl/ 1:100,000 Epinephrine			P-value
	Baseline	Visit	Change	Baseline	Visit	Change	
<b>Standing Systolic Blood Pressure (mmHg)</b>							
<b>Baseline</b>							
N	882			441			0.509
MEAN	125.9			124.7			
SEM	0.61			0.84			
MEDIAN	123.0			122.0			
MIN							
MAX							
<b>Post Dental Procedure</b>							
N	871	871	871	433	433	433	0.309
MEAN	125.7	126.4	0.7	124.7	126.0	1.4	
SEM	0.61	0.61	0.47	0.85	0.89	0.62	
MEDIAN	123.0	124.0	0.0	122.0	122.0	0.0	
MIN							
MAX							

The two-sided p-value is from an ANOVA with treatment, age group, center, strata, treatment-by-center interaction and treatment-by-strata interaction effects, comparing treatment groups.



Table 4.1.1  
 Summary of Mean Change From Baseline in Vital Signs  
 Protocols S96001.02, S96002.01 and S96001.02UK  
 All Treated Patients

	4X Articaine HCl/ 1:100,000 Epinephrine			2X Lidocaine HCl/ 1:100,000 Epinephrine			P-value
	Baseline	Visit	Change	Baseline	Visit	Change	
<b>Standing Diastolic Blood Pressure (mmHg)</b>							
<b>Baseline</b>							
N	882			441			
MEAN	80.5			80.6			0.862
SEM	0.41			0.57			
MEDIAN	80.0			80.0			
MIN							
MAX							
<b>Post Dental Procedure</b>							
N	871	871	871	433	433	433	
MEAN	80.3	80.3	-0.1	80.5	81.2	0.7	0.265
SEM	0.41	0.41	0.34	0.58	0.61	0.49	
MEDIAN	80.0	80.0	0.0	80.0	80.0	0.0	
MIN							
MAX							

The two-sided p-value is from an ANOVA with treatment, age group, center, strata, treatment-by-center interaction and treatment-by-strata interaction effects, comparing treatment groups.

Table 4.1.1  
Summary of Mean Change From Baseline in Vital Signs  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine			2% Lidocaine HCl/ 1:100,000 Epinephrine			P-value
	Baseline	Visit	Change	Baseline	Visit	Change	
<b>Pulse (BPM)</b>							
<b>Baseline</b>							
N	882			443			0.247
MEAN	74.0			74.3			
SEM	0.43			0.60			
MEDIAN	72.0			74.0			
MIN MAX							
<b>One Minute Post-therapy</b>							
N	882	882	882	442	442	442	0.522
MEAN	74.0	75.7	1.7	74.3	76.7	2.4	
SEM	0.43	0.44	0.32	0.60	0.65	0.46	
MEDIAN	72.0	75.0	1.0	73.5	76.0	1.5	
MIN MAX							
<b>Five Minutes Post-therapy</b>							
N	880	880	880	442	442	442	0.469
MEAN	74.0	75.8	1.8	74.3	76.0	1.7	
SEM	0.43	0.44	0.32	0.60	0.61	0.44	
MEDIAN	72.0	75.0	1.0	73.5	75.0	1.0	
MIN MAX							

The two-sided p-value is from an ANOVA with treatment, age group, center, strata, treatment-by-center interaction and treatment-by-strata interaction effects, comparing treatment groups.

Table 4.1.1  
Summary of Mean Change From Baseline in Vital Signs  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

	4X Articaine HCl/ 1:100,000 Epinephrine			2X Lidocaine HCl/ 1:100,000 Epinephrine			P-value
	Baseline	Visit	Change	Baseline	Visit	Change	
Post Dental Procedure							
N	881	881	881	442	442	442	
MEAN	74.0	72.9	-1.1	74.3	73.0	-1.2	0.618
SEM	0.43	0.40	0.34	0.60	0.59	0.45	
MEDIAN	72.0	72.0	-1.0	73.5	71.0	-1.0	
MIN							
MAX							

The two-sided p-value is from an ANOVA with treatment, age group, center, strata, treatment-by-center interaction and treatment-by-strata interaction effects, comparing treatment groups.

Table 4.1.1  
Summary of Mean Change From Baseline in Vital Signs  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine			2% Lidocaine HCl/ 1:100,000 Epinephrine			P-value
	Baseline	Visit	Change	Baseline	Visit	Change	
<b>Respirations (/minute)</b>							
<b>Baseline</b>							
N	880			443			
MEAN	17.2			17.0			0.244
SEM	0.12			0.16			
MEDIAN	16.0			16.0			
MIN							
MAX							
<b>One Minute Post-therapy</b>							
N	880	880	880	442	442	442	
MEAN	17.2	17.7	0.5	17.0	17.6	0.5	0.804
SEM	0.12	0.12	0.08	0.16	0.17	0.12	
MEDIAN	16.0	18.0	0.0	16.0	17.0	0.0	
MIN							
MAX							
<b>Five Minutes Post-therapy</b>							
N	877	877	877	442	442	442	
MEAN	17.2	17.5	0.3	17.0	17.2	0.2	0.643
SEM	0.12	0.12	0.08	0.16	0.16	0.11	
MEDIAN	16.0	18.0	0.0	16.0	17.0	0.0	
MIN							
MAX							

The two-sided p-value is from an ANOVA with treatment, age group, center, strata, treatment-by-center interaction and treatment-by-strata interaction effects, comparing treatment groups.

Table 4.1.1  
Summary of Mean Change From Baseline in Vital Signs  
Protocols S96001.02, S96002.01 and S96001.02UK  
All Treated Patients

	4% Articaine HCl/ 1:100,000 Epinephrine			2% Lidocaine HCl/ 1:100,000 Epinephrine			P-value
	Baseline	Visit	Change	Baseline	Visit	Change	
Post Dental Procedure							
N	878	878	878	441	441	441	
MEAN	17.2	17.1	-0.1	17.0	17.1	0.1	0.240
SEM	0.12	0.11	0.08	0.16	0.16	0.11	
MEDIAN	16.0	17.0	0.0	16.0	17.0	0.0	
MIN							
MAX							

The two-sided p-value is from an ANOVA with treatment, age group, center, strata, treatment-by-center interaction and treatment-by-strata interaction effects, comparing treatment groups.