Core Augmentation (Clinical Data Tables Only)

CORE STUDY - AUGMENTATION

Table 19: Patient Compliance Through 3 Years

	0-4 Weeks	6 Months	1 Year	2 Years	3 Years
Theoretically Due	494	494	494	494	410
Deaths*	0	0	0	0	1
Explant-Related Discontinuations*	0	1	3	5	11
Without Replacement	0	0	0	1	3
Replacement with Non-Study Device	0	1	2	2	5
Unknown Replacement Status	0	0	1	2	3
Expected	494	493	491	489	398
Actual Evaluated	488	416	422	440	322
Lost-to-Follow-Up	6	77	69	49	76
% Follow-Up	99.8%	84.4%	85.9%	90.0%	80.9%

* Deaths and Explant-Related Discontinuations are reported cumulatively.

Attachment 2

CORE STUDY - AUGMENTATION

Table 20: Patient Discontinuation Through 3 Years

	Patients (N = 494)	
Discontinuation	n	%
Not Discontinued	475	96.2%
Discontinued		
Death	1	0.2%
Explanted of All Study Devices	13	2.6%
Patient Choice	5	1.0%
	494	100.0%

Attachment 2

CORE STUDY - AUGMENTATION

Table 20 (cont.): Patient Discontinuation Through 3 Years

Patient Choice Discontinuation Specified (N = 5)

Pt Seq#	Patient Choice Discontinuation
001	PATIENT MOVED TO NEW YORK.DOES NOT WANT TO BE TRANSFERRED
002	PT.LIVES IN EUROPE,NO LONGER WISHES TO PARTICIPATE.HAS NOT BEEN HERE SINCE 1999
003	DISTANCE TO TRAVEL.4 CHILDREN,1 SICK
004	NO LONGER WISHES TO COMPLY
005	PT REQUESTS SHE BE DISCONTINUED. PT REFUSES TO COME FOR FOLLOW-UP

Death Reason Specified (N = 1)

Pt Seq#	Death Reason Specified
001	NO INFORMATION

CORE STUDY - AUGMENTATION

Table 21: Risk of First Occurrence of Asymmetry (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	4	478	0.8% (0.0%, 1.6%)		N/A	
6 Months	6	469	1.2% (0.3%, 2.2%)		N/A	
1 Year	7	457	1.5% (0.4%, 2.5%)		N/A	
2 Years	12	424	2.6% (1.1%, 4.0%)		N/A	
3 Years	13	307	2.8% (1.3%, 4.4%)		N/A	

CORE STUDY - AUGMENTATION

Table 22: Incidence and Prevalence of Asymmetry (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	4 (0.8%)	4 (0.8%)	493		N/A	
6 Months	2 (0.4%)	6 (1.2%)	482		N/A	
1 Year	1 (0.2%)	5 (1.1%)	475		N/A	
2 Years	5 (1.1%)	8 (1.7%)	464		N/A	
3 Years	1 (0.2%)	7 (1.6%)	435		N/A	

CORE STUDY - AUGMENTATION

Table 23: Time to Resolution of Asymmetry (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 5)	
Minimum	1
Median	728
Mean	531
Maximum	1006
Resolved - Time To Resolution (N = 8)*	
Minimum	59
Median	142
Mean	244
Maximum	700
Combined - Time To Resolution (N = 13)	
Minimum	1
Median	207
Mean	354
Maximum	1006

* Includes 1 occurrence of Asymmetry that was resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 24: Distribution of Asymmetry Resolution Status
(>= Moderate Severity)

Resolution Status	By Patient n	By Patient %(N = 13)
Not Yet Resolved		
Undergoing Treatment	3	23.1%
Treatment Not Possible	1	7.7%
Refused Treatment	1	7.7%
Total	5	38.5%
Resolved*		
With Reoperation and Explantation	2	15.4%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	4	30.8%
Without Treatment	2	15.4%
Total	8	61.5%

* Includes 1 occurrence of Asymmetry that was resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 25: Risk of First Occurrence of Breast Pain (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	18	465	3.7% (2.0%, 5.3%)	26	939	2.7% (1.6%, 3.7%)
6 Months	21	457	4.3% (2.5%, 6.1%)	29	925	3.0% (1.9%, 4.0%)
1 Year	23	445	4.7% (2.8%, 6.6%)	31	901	3.2% (2.1%, 4.3%)
2 Years	27	415	5.6% (3.6%, 7.7%)	35	842	3.6% (2.4%, 4.8%)
3 Years	29	297	6.2% (4.0%, 8.4%)	40	600	4.4% (3.0%, 5.7%)

CORE STUDY - AUGMENTATION

Table 26: Incidence and Prevalence of Breast Pain (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	18 (3.7%)	18 (3.7%)	493	26 (2.6%)	26 (2.6%)	985
6 Months	3 (0.6%)	9 (1.9%)	482	3 (0.3%)	11 (1.1%)	963
1 Year	2 (0.4%)	6 (1.3%)	475	2 (0.2%)	7 (0.7%)	948
2 Years	4 (0.9%)	7 (1.5%)	464	4 (0.4%)	7 (0.8%)	925
3 Years	2 (0.5%)	7 (1.6%)	435	5 (0.6%)	10 (1.2%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 27: Time to Resolution of Breast Pain (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 7)	
Minimum	112
Median	466
Mean	485
Maximum	934
Resolved - Time To Resolution (N = 22)	
Minimum	1
Median	7
Mean	51
Maximum	206
Combined - Time To Resolution (N = 29)	
Minimum	1
Median	44
Mean	156
Maximum	934

CORE STUDY - AUGMENTATION

Table 28: Distribution of Breast Pain Resolution Status
(>= Moderate Severity)

	By Patient	
Resolution Status	n	%(N = 29)
Not Yet Resolved		
Undergoing Treatment	6	20.7%
Treatment Not Possible	0	0.0%
Refused Treatment	1	3.4%
Total	7	24.1%
Resolved		
With Reoperation and Explantation	1	3.4%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	6	20.7%
Without Treatment	15	51.7%
Total	22	75.9%

CORE STUDY - AUGMENTATION

Table 29A: Risk of First Occurrence of Bruising (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	5	478	1.0% (0.1%, 1.9%)	9	956	0.9% (0.3%, 1.5%)
6 Months	5	471	1.0% (0.1%, 1.9%)	9	941	0.9% (0.3%, 1.5%)
1 Year	6	459	1.2% (0.3%, 2.2%)	10	917	1.0% (0.4%, 1.7%)
2 Years	6	432	1.2% (0.3%, 2.2%)	10	861	1.0% (0.4%, 1.7%)
3 Years	6	310	1.2% (0.3%, 2.2%)	10	618	1.0% (0.4%, 1.7%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 29B: Risk of First Occurrence of Bruising (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	41	442	8.4% (5.9%,10.8%)	78	887	8.0% (6.3%, 9.6%)
6 Months	42	435	8.6% (6.1%,11.0%)	79	873	8.1% (6.4%, 9.8%)
1 Year	43	423	8.8% (6.3%,11.3%)	81	848	8.3% (6.5%,10.0%)
2 Years	43	398	8.8% (6.3%,11.3%)	81	797	8.3% (6.5%,10.0%)
3 Years	45	291	9.3% (6.7%,11.9%)	85	582	8.8% (7.0%,10.6%)

CORE STUDY - AUGMENTATION

Table 30A: Incidence and Prevalence of Bruising (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	5 (1.0%)	5 (1.0%)	493	9 (0.9%)	9 (0.9%)	985
6 Months	0 (0.0%)	2 (0.4%)	482	0 (0.0%)	4 (0.4%)	963
1 Year	1 (0.2%)	1 (0.2%)	475	1 (0.1%)	1 (0.1%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 30B: Incidence and Prevalence of Bruising (All Severity Levels)

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	41 (8.3%)	41 (8.3%)	493	78 (7.9%)	78 (7.9%)	985
6 Months	1 (0.2%)	7 (1.5%)	482	1 (0.1%)	13 (1.3%)	963
1 Year	1 (0.2%)	2 (0.4%)	475	2 (0.2%)	4 (0.4%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	2 (0.5%)	2 (0.5%)	435	4 (0.5%)	4 (0.5%)	866

CORE STUDY - AUGMENTATION

Table 31A: Time to Resolution of Bruising (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 6)	
Minimum	1
Median	26
Mean	25
Maximum	57
Combined - Time To Resolution (N = 6)	
Minimum	1
Median	26
Mean	25
Maximum	57

CORE STUDY - AUGMENTATION

Table 31B: Time to Resolution of Bruising (All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 45)	
Minimum	1
Median	6
Mean	14
Maximum	188
Combined - Time To Resolution (N = 45)	
Minimum	1
Median	6
Mean	14
Maximum	188

CORE STUDY - AUGMENTATION

Table 32A: Distribution of Bruising Resolution Status
(>= Moderate Severity)

Resolution Status	By Patient	
	n	%(N = 6)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	33.3%
Without Treatment	4	66.7%
Total	6	100.0%

CORE STUDY - AUGMENTATION

Table 32B: Distribution of Bruising Resolution Status (All Severity Levels)

Resolution Status	By Patient	
	n	%(N = 45)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	4.4%
Without Treatment	43	95.6%
Total	45	100.0%

CORE STUDY - AUGMENTATION

Table 33: Risk of First Occurrence of Capsule Calcification (>= Moderate Severity)

	By Patient				By Implant			
	Number Affected	Number Remaining		Cumulative Risk	Number Affected	Number Remaining		Cumulative Risk
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	482	0.0%	--	0	963	0.0%	--
6 Months	0	475	0.0%	--	0	948	0.0%	--
1 Year	0	464	0.0%	--	0	925	0.0%	--
2 Years	1	435	0.2%	(0.0%, 0.7%)	1	866	0.1%	(0.0%, 0.3%)
3 Years	1	312	0.2%	(0.0%, 0.7%)	1	621	0.1%	(0.0%, 0.3%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 34: Incidence and Prevalence of Capsule Calcification (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	482	0 (0.0%)	0 (0.0%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	1 (0.2%)	1 (0.2%)	464	1 (0.1%)	1 (0.1%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

Attachment 2

Attachment 2

CORE STUDY - AUGMENTATION

Table 35: Time to Resolution of Capsule Calcification (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	42
Median	42
Mean	42
Maximum	42
Resolved - Time To Resolution (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Combined - Time To Resolution (N = 1)	
Minimum	42
Median	42
Mean	42
Maximum	42

CORE STUDY - AUGMENTATION

Table 36: Distribution of Capsule Calcification Resolution Status
(>= Moderate Severity)

	By Patient	
Resolution Status	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	1	100.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	100.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	0	0.0%

CORE STUDY - AUGMENTATION

Table 37: Risk of First Occurrence of Capsular Contracture (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	480	0.4% (0.0%, 1.0%)	4	959	0.4% (0.0%, 0.8%)
6 Months	17	461	3.5% (1.9%, 5.2%)	26	929	2.7% (1.7%, 3.7%)
1 Year	30	441	6.3% (4.1%, 8.4%)	45	893	4.7% (3.4%, 6.1%)
2 Years	33	412	6.9% (4.6%, 9.2%)	49	835	5.2% (3.7%, 6.6%)
3 Years	38	295	8.3% (5.8%,10.9%)	57	598	6.3% (4.7%, 7.9%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 38: Incidence and Prevalence of Capsular Contracture (>= Moderate Severity)

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.4%)	2 (0.4%)	493	4 (0.4%)	4 (0.4%)	985
6 Months	15 (3.1%)	17 (3.5%)	482	22 (2.3%)	26 (2.7%)	963
1 Year	13 (2.7%)	22 (4.6%)	475	19 (2.0%)	32 (3.4%)	948
2 Years	3 (0.6%)	13 (2.8%)	464	4 (0.4%)	19 (2.1%)	925
3 Years	5 (1.1%)	9 (2.1%)	435	8 (0.9%)	15 (1.7%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 39: Time to Resolution of Capsular Contracture (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 10)	
Minimum	99
Median	388
Mean	453
Maximum	1086
Resolved - Time To Resolution (N = 28)*	
Minimum	1
Median	67
Mean	166
Maximum	1038
Combined - Time To Resolution (N = 38)	
Minimum	1
Median	144
Mean	242
Maximum	1086

* Includes 4 occurrences of Capsular Contracture that were resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 40: Distribution of Capsular Contracture Resolution Status
(>= Moderate Severity)

Resolution Status	By Patient n	By Patient %(N = 38)
Not Yet Resolved		
Undergoing Treatment	10	26.3%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	10	26.3%
Resolved*		
With Reoperation and Explantation	7	18.4%
With Reoperation Without Explantation	12	31.6%
With Non-Surgical Treatment	4	10.5%
Without Treatment	5	13.2%
Total	28	73.7%

* Includes 4 occurrences of Capsular Contracture that were resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 41: Risk of First Occurrence of Delayed Wound Healing (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	480	0.4% (0.0%, 1.0%)	3	960	0.3% (0.0%, 0.7%)
6 Months	3	472	0.6% (0.0%, 1.3%)	4	944	0.4% (0.0%, 0.8%)
1 Year	4	460	0.8% (0.0%, 1.6%)	5	920	0.5% (0.1%, 1.0%)
2 Years	4	432	0.8% (0.0%, 1.6%)	5	862	0.5% (0.1%, 1.0%)
3 Years	5	310	1.1% (0.1%, 2.1%)	6	619	0.7% (0.1%, 1.2%)

CORE STUDY - AUGMENTATION

Table 42: Incidence and Prevalence of Delayed Wound Healing (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.4%)	2 (0.4%)	493	3 (0.3%)	3 (0.3%)	985
6 Months	1 (0.2%)	1 (0.2%)	482	1 (0.1%)	1 (0.1%)	963
1 Year	1 (0.2%)	2 (0.4%)	475	1 (0.1%)	2 (0.2%)	948
2 Years	0 (0.0%)	1 (0.2%)	464	0 (0.0%)	1 (0.1%)	925
3 Years	1 (0.2%)	2 (0.5%)	435	1 (0.1%)	2 (0.2%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 43: Time to Resolution of Delayed Wound Healing (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 2)	
Minimum	371
Median	543
Mean	543
Maximum	714
Resolved - Time To Resolution (N = 3)	
Minimum	1
Median	8
Mean	22
Maximum	57
Combined - Time To Resolution (N = 5)	
Minimum	1
Median	57
Mean	230
Maximum	714

CORE STUDY - AUGMENTATION

Table 44: Distribution of Delayed Wound Healing Resolution Status
(>= Moderate Severity)

Resolution Status	By Patient	
	n	%(N = 5)
Not Yet Resolved		
Undergoing Treatment	2	40.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	2	40.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	1	20.0%
With Non-Surgical Treatment	1	20.0%
Without Treatment	1	20.0%
Total	3	60.0%

CORE STUDY - AUGMENTATION

Table 45: Risk of First Occurrence of Fluid Accumulation

N/A: FLUID ACCUMULATION HAS BEEN COMBINED WITH SEROMA

CORE STUDY - AUGMENTATION

Table 46: Incidence and Prevalence of Fluid Accumulation (>= Moderate Severity)

N/A: FLUID ACCUMULATION HAS BEEN COMBINED WITH SEROMA

CORE STUDY - AUGMENTATION

Table 47: Time to Resolution of Fluid Accumulation

N/A: FLUID ACCUMULATION HAS BEEN COMBINED WITH SEROMA

CORE STUDY - AUGMENTATION

Table 48: Distribution of Fluid Accumulation Resolution Status

N/A: FLUID ACCUMULATION HAS BEEN COMBINED WITH SEROMA

CORE STUDY - AUGMENTATION

Table 49A: Risk of First Occurrence of Hematoma (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	4	478	0.8% (0.0%, 1.6%)	4	959	0.4% (0.0%, 0.8%)
6 Months	4	471	0.8% (0.0%, 1.6%)	4	944	0.4% (0.0%, 0.8%)
1 Year	4	460	0.8% (0.0%, 1.6%)	4	921	0.4% (0.0%, 0.8%)
2 Years	4	431	0.8% (0.0%, 1.6%)	4	862	0.4% (0.0%, 0.8%)
3 Years	4	309	0.8% (0.0%, 1.6%)	4	618	0.4% (0.0%, 0.8%)

CORE STUDY - AUGMENTATION

Table 49B: Risk of First Occurrence of Hematoma (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	4	478	0.8% (0.0%, 1.6%)	4	959	0.4% (0.0%, 0.8%)
6 Months	5	470	1.0% (0.1%, 1.9%)	5	943	0.5% (0.1%, 1.0%)
1 Year	5	459	1.0% (0.1%, 1.9%)	5	920	0.5% (0.1%, 1.0%)
2 Years	5	430	1.0% (0.1%, 1.9%)	5	861	0.5% (0.1%, 1.0%)
3 Years	5	308	1.0% (0.1%, 1.9%)	5	617	0.5% (0.1%, 1.0%)

CORE STUDY - AUGMENTATION

Table 50A: Incidence and Prevalence of Hematoma (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	4 (0.8%)	4 (0.8%)	493	4 (0.4%)	4 (0.4%)	985
6 Months	0 (0.0%)	0 (0.0%)	482	0 (0.0%)	0 (0.0%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 50B: Incidence and Prevalence of Hematoma (All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	4 (0.8%)	4 (0.8%)	493	4 (0.4%)	4 (0.4%)	985
6 Months	1 (0.2%)	1 (0.2%)	482	1 (0.1%)	1 (0.1%)	963
1 Year	0 (0.0%)	1 (0.2%)	475	0 (0.0%)	1 (0.1%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 51A: Time to Resolution of Hematoma (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 4)	
Minimum	1
Median	6
Mean	5
Maximum	7
Combined - Time To Resolution (N = 4)	
Minimum	1
Median	6
Mean	5
Maximum	7

Attachment 2

CORE STUDY - AUGMENTATION

Table 51B: Time to Resolution of Hematoma (All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 5)	
Minimum	1
Median	7
Mean	60
Maximum	281
Combined - Time To Resolution (N = 5)	
Minimum	1
Median	7
Mean	60
Maximum	281

Attachment 2

CORE STUDY - AUGMENTATION

Table 52A: Distribution of Hematoma Resolution Status
(>= Moderate Severity)

Resolution Status	By Patient	
	n	%(N = 4)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	4	100.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	4	100.0%

Attachment 2

CORE STUDY - AUGMENTATION

Table 52B: Distribution of Hematoma Resolution Status (All Severity Levels)

Resolution Status	By Patient	
	n	%(N = 5)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	4	80.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	1	20.0%
Total	5	100.0%

Attachment 2

CORE STUDY - AUGMENTATION

Table 53: Risk of First Occurrence of Hypertrophic Scarring

N/A: HYPERTROPHIC SCARRING HAS BEEN COMBINED WITH OTHER ABNORMAL SCARRING

CORE STUDY - AUGMENTATION

Table 54: Incidence and Prevalence of Hypertrophic Scarring

N/A: HYPERTROPHIC SCARRING HAS BEEN COMBINED WITH OTHER ABNORMAL SCARRING

CORE STUDY - AUGMENTATION

Table 55: Time to Resolution of Hypertrophic Scarring

N/A: HYPERTROPHIC SCARRING HAS BEEN COMBINED WITH OTHER ABNORMAL SCARRING

CORE STUDY - AUGMENTATION

Table 56: Distribution of Hypertrophic Scarring Resolution Status

N/A: HYPERTROPHIC SCARRING HAS BEEN COMBINED WITH OTHER ABNORMAL SCARRING

CORE STUDY - AUGMENTATION

Table 57: Risk of First Occurrence of Implant Extrusion (All Severity Levels)

	By Patient				By Implant			
	Number Affected	Number Remaining		Cumulative Risk	Number Affected	Number Remaining		Cumulative Risk
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	482	0.0%	--	0	963	0.0%	--
6 Months	1	475	0.2%	(0.0%, 0.6%)	1	948	0.1%	(0.0%, 0.3%)
1 Year	1	464	0.2%	(0.0%, 0.6%)	1	925	0.1%	(0.0%, 0.3%)
2 Years	1	435	0.2%	(0.0%, 0.6%)	1	866	0.1%	(0.0%, 0.3%)
3 Years	1	312	0.2%	(0.0%, 0.6%)	1	621	0.1%	(0.0%, 0.3%)

CORE STUDY - AUGMENTATION

Table 58: Incidence and Prevalence of Implant Extrusion (All Severity Levels)

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	1 (0.2%)	1 (0.2%)	482	1 (0.1%)	1 (0.1%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

CORE STUDY - AUGMENTATION

Table 59: Time to Resolution of Implant Extrusion (All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 1)*	
Minimum	3
Median	3
Mean	3
Maximum	3
Combined - Time To Resolution (N = 1)	
Minimum	3
Median	3
Mean	3
Maximum	3

* Includes 1 occurrence of Implant Extrusion that was resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 60: Distribution of Implant Extrusion Resolution Status
(All Severity Levels)

Resolution Status	By Patient n	By Patient %(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved*		
With Reoperation and Explantation	1	100.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	1	100.0%

* Includes 1 occurrence of Implant Extrusion that was resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 61: Risk of First Occurrence of Implant Malposition (>= Moderate Severity)

	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	3	479	0.6%	(0.0%, 1.3%)	4	959	0.4%	(0.0%, 0.8%)
6 Months	8	468	1.7%	(0.5%, 2.8%)	12	938	1.3%	(0.5%, 1.9%)
1 Year	10	455	2.1%	(0.8%, 3.4%)	15	912	1.6%	(0.8%, 2.4%)
2 Years	12	425	2.5%	(1.1%, 3.9%)	18	851	1.9%	(1.0%, 2.8%)
3 Years	14	303	3.1%	(1.5%, 4.8%)	21	608	2.4%	(1.3%, 3.4%)

CORE STUDY - AUGMENTATION

Table 62: Incidence and Prevalence of Implant Malposition (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	3 (0.6%)	3 (0.6%)	493	4 (0.4%)	4 (0.4%)	985
6 Months	5 (1.0%)	8 (1.7%)	482	8 (0.8%)	12 (1.2%)	963
1 Year	2 (0.4%)	5 (1.1%)	475	3 (0.3%)	7 (0.7%)	948
2 Years	2 (0.4%)	6 (1.3%)	464	3 (0.3%)	7 (0.8%)	925
3 Years	2 (0.5%)	5 (1.1%)	435	3 (0.3%)	7 (0.8%)	866

CORE STUDY - AUGMENTATION

Table 63: Time to Resolution of Implant Malposition (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 3)	
Minimum	104
Median	354
Mean	375
Maximum	666
Resolved - Time To Resolution (N = 11)	
Minimum	1
Median	78
Mean	174
Maximum	666
Combined - Time To Resolution (N = 14)	
Minimum	1
Median	113
Mean	217
Maximum	666

CORE STUDY - AUGMENTATION

Table 64: Distribution of Implant Malposition Resolution Status
(>= Moderate Severity)

Resolution Status	By Patient	
	n	%(N = 14)
Not Yet Resolved		
Undergoing Treatment	3	21.4%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	3	21.4%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	7	50.0%
With Non-Surgical Treatment	1	7.1%
Without Treatment	3	21.4%
Total	11	78.6%

CORE STUDY - AUGMENTATION

Table 65: Risk of First Occurrence of Implant Palpability

N/A: IMPLANT PALPABILITY HAS BEEN COMBINED WITH IMPLANT VISIBILITY

CORE STUDY - AUGMENTATION

Table 66: Incidence and Prevalence of Implant Palpability

N/A: IMPLANT PALPABILITY HAS BEEN COMBINED WITH IMPLANT VISIBILITY

CORE STUDY - AUGMENTATION

Table 67: Time to Resolution of Implant Palpability

N/A: IMPLANT PALPABILITY HAS BEEN COMBINED WITH IMPLANT VISIBILITY

Attachment 2

CORE STUDY - AUGMENTATION

Table 68: Distribution of Implant Palpability Resolution Status

N/A: IMPLANT PALPABILITY HAS BEEN COMBINED WITH IMPLANT VISIBILITY

CORE STUDY - AUGMENTATION

Table 69: Risk of First Occurrence of Implant Palpability / Visibility (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	1	481	0.2% (0.0%, 0.6%)	1	962	0.1% (0.0%, 0.3%)
6 Months	3	472	0.6% (0.0%, 1.3%)	4	944	0.4% (0.0%, 0.8%)
1 Year	3	461	0.6% (0.0%, 1.3%)	4	921	0.4% (0.0%, 0.8%)
2 Years	3	433	0.6% (0.0%, 1.3%)	4	863	0.4% (0.0%, 0.8%)
3 Years	3	311	0.6% (0.0%, 1.3%)	4	619	0.4% (0.0%, 0.8%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 70: Incidence and Prevalence of Implant Palpability / Visibility
(>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.2%)	1 (0.2%)	493	1 (0.1%)	1 (0.1%)	985
6 Months	2 (0.4%)	3 (0.6%)	482	3 (0.3%)	4 (0.4%)	963
1 Year	0 (0.0%)	3 (0.6%)	475	0 (0.0%)	4 (0.4%)	948
2 Years	0 (0.0%)	3 (0.6%)	464	0 (0.0%)	4 (0.4%)	925
3 Years	0 (0.0%)	1 (0.2%)	435	0 (0.0%)	2 (0.2%)	866

CORE STUDY - AUGMENTATION

Table 71: Time to Resolution of Implant Palpability / Visibility
(>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 2)	
Minimum	579
Median	801
Mean	801
Maximum	1022
Resolved - Time To Resolution (N = 1)	
Minimum	375
Median	375
Mean	375
Maximum	375
Combined - Time To Resolution (N = 3)	
Minimum	375
Median	579
Mean	659
Maximum	1022

CORE STUDY - AUGMENTATION

Table 72: Distribution of Implant Palpability / Visibility Resolution Status (>= Moderate Severity)

	By Patient	
Resolution Status	n	%(N = 3)
Not Yet Resolved		
Undergoing Treatment	1	33.3%
Treatment Not Possible	1	33.3%
Refused Treatment	0	0.0%
Total	2	66.7%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	1	33.3%
Total	1	33.3%

CORE STUDY - AUGMENTATION

Table 73A: Risk of First Occurrence of Infection (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	1	481	0.2% (0.0%, 0.6%)	2	961	0.2% (0.0%, 0.5%)
6 Months	1	474	0.2% (0.0%, 0.6%)	2	946	0.2% (0.0%, 0.5%)
1 Year	1	463	0.2% (0.0%, 0.6%)	2	923	0.2% (0.0%, 0.5%)
2 Years	1	435	0.2% (0.0%, 0.6%)	2	866	0.2% (0.0%, 0.5%)
3 Years	1	312	0.2% (0.0%, 0.6%)	2	621	0.2% (0.0%, 0.5%)

CORE STUDY - AUGMENTATION

Table 73B: Risk of First Occurrence of Infection (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	480	0.4% (0.0%, 1.0%)	4	959	0.4% (0.0%, 0.8%)
6 Months	5	470	1.0% (0.1%, 1.9%)	7	941	0.7% (0.2%, 1.3%)
1 Year	5	459	1.0% (0.1%, 1.9%)	7	918	0.7% (0.2%, 1.3%)
2 Years	5	431	1.0% (0.1%, 1.9%)	7	861	0.7% (0.2%, 1.3%)
3 Years	5	309	1.0% (0.1%, 1.9%)	7	617	0.7% (0.2%, 1.3%)

CORE STUDY - AUGMENTATION

Table 74A: Incidence and Prevalence of Infection (>= Moderate Severity)

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.2%)	1 (0.2%)	493	2 (0.2%)	2 (0.2%)	985
6 Months	0 (0.0%)	1 (0.2%)	482	0 (0.0%)	2 (0.2%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

CORE STUDY - AUGMENTATION

Table 74B: Incidence and Prevalence of Infection (All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.4%)	2 (0.4%)	493	4 (0.4%)	4 (0.4%)	985
6 Months	3 (0.6%)	4 (0.8%)	482	3 (0.3%)	5 (0.5%)	963
1 Year	0 (0.0%)	3 (0.6%)	475	0 (0.0%)	3 (0.3%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 75A: Time to Resolution of Infection (>= Moderate Severity)

	Measurement in Days
Resolution	By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 1)	
Minimum	25
Median	25
Mean	25
Maximum	25
Combined - Time To Resolution (N = 1)	
Minimum	25
Median	25
Mean	25
Maximum	25

Attachment 2

CORE STUDY - AUGMENTATION

Table 75B: Time to Resolution of Infection (All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 5)	
Minimum	13
Median	107
Mean	84
Maximum	143
Combined - Time To Resolution (N = 5)	
Minimum	13
Median	107
Mean	84
Maximum	143

Attachment 2

CORE STUDY - AUGMENTATION

Table 76A: Distribution of Infection Resolution Status
(>= Moderate Severity)

	By Patient	
Resolution Status	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	1	100.0%
Total	1	100.0%

CORE STUDY - AUGMENTATION

Table 76B: Distribution of Infection Resolution Status
(All Severity Levels)

Resolution Status	By Patient n	By Patient %(N = 5)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	40.0%
Without Treatment	3	60.0%
Total	5	100.0%

CORE STUDY - AUGMENTATION

Table 77: Risk of First Occurrence of Irritation (>= Moderate Severity)

	By Patient				By Implant			
	Number Affected	Number Remaining		Cumulative Risk	Number Affected	Number Remaining		Cumulative Risk
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	482	0.0%	--	0	963	0.0%	--
6 Months	0	475	0.0%	--	0	948	0.0%	--
1 Year	0	464	0.0%	--	0	925	0.0%	--
2 Years	0	435	0.0%	--	0	866	0.0%	--
3 Years	0	312	0.0%	--	0	621	0.0%	--

CORE STUDY - AUGMENTATION

Table 78: Incidence and Prevalence of Irritation (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	482	0 (0.0%)	0 (0.0%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

CORE STUDY - AUGMENTATION

Table 79: Time to Resolution of Irritation (>= Moderate Severity)

THERE WAS NO IRRITATION OBSERVED AMONG AUGMENTATION PATIENTS

Attachment 2

CORE STUDY - AUGMENTATION

Table 80: Distribution of Irritation Resolution Status (>= Moderate Severity)

THERE WAS NO IRRITATION OBSERVED AMONG AUGMENTATION PATIENTS

CORE STUDY - AUGMENTATION

Table 81: Risk of First Occurrence of Loss of Nipple Sensation

N/A: LOSS OF NIPPLE SENSATION HAS BEEN COMBINED WITH NIPPLE HYPERSENSITIVITY AND NIPPLE PARESTHESIA

CORE STUDY - AUGMENTATION

Table 82: Incidence and Prevalence of Loss of Nipple Sensation

N/A: LOSS OF NIPPLE SENSATION HAS BEEN COMBINED WITH NIPPLE HYPERSENSITIVITY AND NIPPLE PARESTHESIA

CORE STUDY - AUGMENTATION

Table 83: Time to Resolution of Loss of Nipple Sensation

N/A: LOSS OF NIPPLE SENSATION HAS BEEN COMBINED WITH NIPPLE HYPERSENSITIVITY AND NIPPLE PARESTHESIA

CORE STUDY - AUGMENTATION

Table 84: Distribution of Loss of Nipple Sensation Resolution Status

N/A: LOSS OF NIPPLE SENSATION HAS BEEN COMBINED WITH NIPPLE HYPERSENSITIVITY AND NIPPLE PARESTHESIA

CORE STUDY - AUGMENTATION

Table 85: Risk of First Occurrence of Loss of Skin Sensation

N/A: LOSS OF SKIN SENSATION HAS BEEN COMBINED WITH SKIN HYPERSENSITIVITY AND SKIN PARESTHESIA

Attachment 2

CORE STUDY - AUGMENTATION

Table 86: Incidence and Prevalence of Loss of Skin Sensation

N/A: LOSS OF SKIN SENSATION HAS BEEN COMBINED WITH SKIN HYPERSENSITIVITY AND SKIN PARESTHESIA

CORE STUDY - AUGMENTATION

Table 87: Time to Resolution of Loss of Skin Sensation

N/A: LOSS OF SKIN SENSATION HAS BEEN COMBINED WITH SKIN HYPERSENSITIVITY AND SKIN PARESTHESIA

CORE STUDY - AUGMENTATION

Table 88: Distribution of Loss of Skin Sensation Resolution Status

N/A: LOSS OF SKIN SENSATION HAS BEEN COMBINED WITH SKIN HYPERSENSITIVITY AND SKIN PARESTHESIA

CORE STUDY - AUGMENTATION

Table 89A: Risk of First Occurrence of Lymphadenopathy (>= Moderate Severity)

	By Patient				By Implant			
	Number Affected	Number Remaining		Cumulative Risk	Number Affected	Number Remaining		Cumulative Risk
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	482	0.0%	--	0	963	0.0%	--
6 Months	0	475	0.0%	--	0	948	0.0%	--
1 Year	0	464	0.0%	--	0	925	0.0%	--
2 Years	1	434	0.2%	(0.0%, 0.7%)	1	865	0.1%	(0.0%, 0.3%)
3 Years	1	311	0.2%	(0.0%, 0.7%)	1	620	0.1%	(0.0%, 0.3%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 89B: Risk of First Occurrence of Lymphadenopathy (All Severity Levels)

	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	482	0.0%	--	0	963	0.0%	--
6 Months	1	474	0.2%	(0.0%, 0.6%)	2	946	0.2%	(0.0%, 0.5%)
1 Year	1	463	0.2%	(0.0%, 0.6%)	2	923	0.2%	(0.0%, 0.5%)
2 Years	2	433	0.4%	(0.0%, 1.0%)	3	863	0.3%	(0.0%, 0.7%)
3 Years	2	311	0.4%	(0.0%, 1.0%)	3	620	0.3%	(0.0%, 0.7%)

CORE STUDY - AUGMENTATION

Table 90A: Incidence and Prevalence of Lymphadenopathy (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	482	0 (0.0%)	0 (0.0%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	1 (0.2%)	1 (0.2%)	464	1 (0.1%)	1 (0.1%)	925
3 Years	0 (0.0%)	1 (0.2%)	435	0 (0.0%)	1 (0.1%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 90B: Incidence and Prevalence of Lymphadenopathy (All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	1 (0.2%)	1 (0.2%)	482	2 (0.2%)	2 (0.2%)	963
1 Year	0 (0.0%)	1 (0.2%)	475	0 (0.0%)	2 (0.2%)	948
2 Years	1 (0.2%)	1 (0.2%)	464	1 (0.1%)	1 (0.1%)	925
3 Years	0 (0.0%)	1 (0.2%)	435	0 (0.0%)	1 (0.1%)	866

CORE STUDY - AUGMENTATION

Table 91A: Time to Resolution of Lymphadenopathy (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	614
Median	614
Mean	614
Maximum	614
Resolved - Time To Resolution (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Combined - Time To Resolution (N = 1)	
Minimum	614
Median	614
Mean	614
Maximum	614

CORE STUDY - AUGMENTATION

Table 91B: Time to Resolution of Lymphadenopathy (All Severity Levels)

	Measurement in Days
Resolution	By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	614
Median	614
Mean	614
Maximum	614
Resolved - Time To Resolution (N = 1)	
Minimum	84
Median	84
Mean	84
Maximum	84
Combined - Time To Resolution (N = 2)	
Minimum	84
Median	349
Mean	349
Maximum	614

Attachment 2

CORE STUDY - AUGMENTATION

Table 92A: Distribution of Lymphadenopathy Resolution Status
(>= Moderate Severity)

Resolution Status	By Patient n	By Patient %(N = 1)
Not Yet Resolved		
Undergoing Treatment	1	100.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	100.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	0	0.0%

CORE STUDY - AUGMENTATION

Table 92B: Distribution of Lymphadenopathy Resolution Status
(All Severity Levels)

	By Patient	
Resolution Status	n	%(N = 2)
Not Yet Resolved		
Undergoing Treatment	1	50.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	50.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	1	50.0%
Without Treatment	0	0.0%
Total	1	50.0%

CORE STUDY - AUGMENTATION

Table 93A: Risk of First Occurrence of Lymphedema (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	482	0.0% --	0	963	0.0% --
6 Months	1	474	0.2% (0.0%, 0.6%)	1	947	0.1% (0.0%, 0.3%)
1 Year	1	463	0.2% (0.0%, 0.6%)	1	924	0.1% (0.0%, 0.3%)
2 Years	1	434	0.2% (0.0%, 0.6%)	1	866	0.1% (0.0%, 0.3%)
3 Years	1	311	0.2% (0.0%, 0.6%)	1	621	0.1% (0.0%, 0.3%)

CORE STUDY - AUGMENTATION

Table 93B: Risk of First Occurrence of Lymphedema (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	482	0.0% --	0	963	0.0% --
6 Months	1	474	0.2% (0.0%, 0.6%)	1	947	0.1% (0.0%, 0.3%)
1 Year	1	463	0.2% (0.0%, 0.6%)	1	924	0.1% (0.0%, 0.3%)
2 Years	1	434	0.2% (0.0%, 0.6%)	1	866	0.1% (0.0%, 0.3%)
3 Years	1	311	0.2% (0.0%, 0.6%)	1	621	0.1% (0.0%, 0.3%)

CORE STUDY - AUGMENTATION

Table 94A: Incidence and Prevalence of Lymphedema (>= Moderate Severity)

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	1 (0.2%)	1 (0.2%)	482	1 (0.1%)	1 (0.1%)	963
1 Year	0 (0.0%)	1 (0.2%)	475	0 (0.0%)	1 (0.1%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

CORE STUDY - AUGMENTATION

Table 94B: Incidence and Prevalence of Lymphedema (All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	1 (0.2%)	1 (0.2%)	482	1 (0.1%)	1 (0.1%)	963
1 Year	0 (0.0%)	1 (0.2%)	475	0 (0.0%)	1 (0.1%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

CORE STUDY - AUGMENTATION

Table 95A: Time to Resolution of Lymphedema (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 1)	
Minimum	17
Median	17
Mean	17
Maximum	17
Combined - Time To Resolution (N = 1)	
Minimum	17
Median	17
Mean	17
Maximum	17

CORE STUDY - AUGMENTATION

Table 95B: Time to Resolution of Lymphedema (All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 1)	
Minimum	17
Median	17
Mean	17
Maximum	17
Combined - Time To Resolution (N = 1)	
Minimum	17
Median	17
Mean	17
Maximum	17

CORE STUDY - AUGMENTATION

Table 96A: Distribution of Lymphedema Resolution Status
(>= Moderate Severity)

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	1	100.0%
Total	1	100.0%

CORE STUDY - AUGMENTATION

Table 96B: Distribution of Lymphedema Resolution Status
(All Severity Levels)

Resolution Status	By Patient n	By Patient %(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	1	100.0%
Total	1	100.0%

CORE STUDY - AUGMENTATION

Table 97: Risk of First Occurrence of Nipple Hypersensitivity

N/A: NIPPLE HYPERSENSITIVITY HAS BEEN COMBINED WITH LOSS OF NIPPLE SENSATION AND NIPPLE PARESTHESIA

CORE STUDY - AUGMENTATION

Table 98: Incidence and Prevalence of Nipple Hypersensitivity

N/A: NIPPLE HYPERSENSITIVITY HAS BEEN COMBINED WITH LOSS OF NIPPLE SENSATION AND NIPPLE PARESTHESIA

CORE STUDY - AUGMENTATION

Table 99: Time to Resolution of Nipple Hypersensitivity

N/A: NIPPLE HYPERSENSITIVITY HAS BEEN COMBINED WITH LOSS OF NIPPLE SENSATION AND NIPPLE PARESTHESIA

CORE STUDY - AUGMENTATION

Table 100: Distribution of Nipple Hypersensitivity Resolution Status

N/A: NIPPLE HYPERSENSITIVITY HAS BEEN COMBINED WITH LOSS OF NIPPLE SENSATION AND NIPPLE PARESTHESIA

CORE STUDY - AUGMENTATION

Table 101: Risk of First Occurrence of Nipple Hypersensitivity / Paresthesia / Loss of Nipple Sensation (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	13	469	2.7% (1.2%, 4.1%)	21	942	2.2% (1.2%, 3.1%)
6 Months	17	458	3.5% (1.9%, 5.1%)	27	921	2.8% (1.8%, 3.8%)
1 Year	18	447	3.7% (2.0%, 5.4%)	28	899	2.9% (1.8%, 4.0%)
2 Years	19	419	3.9% (2.2%, 5.7%)	30	841	3.1% (2.0%, 4.2%)
3 Years	19	301	3.9% (2.2%, 5.7%)	30	602	3.1% (2.0%, 4.2%)

CORE STUDY - AUGMENTATION

Table 102: Incidence and Prevalence of Nipple Hypersensitivity / Paresthesia / Loss of Nipple Sensation

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	13 (2.6%)	13 (2.6%)	493	21 (2.1%)	21 (2.1%)	985
6 Months	4 (0.8%)	15 (3.1%)	482	6 (0.6%)	24 (2.5%)	963
1 Year	1 (0.2%)	9 (1.9%)	475	1 (0.1%)	13 (1.4%)	948
2 Years	1 (0.2%)	4 (0.9%)	464	2 (0.2%)	5 (0.5%)	925
3 Years	0 (0.0%)	3 (0.7%)	435	0 (0.0%)	4 (0.5%)	866

CORE STUDY - AUGMENTATION

Table 103: Time to Resolution of Nipple Hypersensitivity / Paresthesia / Loss of Nipple Sensation

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 4)	
Minimum	216
Median	695
Mean	589
Maximum	749
Resolved - Time To Resolution (N = 15)	
Minimum	11
Median	58
Mean	109
Maximum	362
Combined - Time To Resolution (N = 19)	
Minimum	11
Median	155
Mean	210
Maximum	749

CORE STUDY - AUGMENTATION

Table 104: Distribution of Nipple Hypersensitivity / Paresthesia / Loss of Nipple Sensation Resolution Status

	By Patient	
Resolution Status	n	%(N = 19)
Not Yet Resolved		
Undergoing Treatment	1	5.3%
Treatment Not Possible	3	15.8%
Refused Treatment	0	0.0%
Total	4	21.1%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	15	78.9%
Total	15	78.9%

CORE STUDY - AUGMENTATION

Table 105A: Risk of First Occurrence of Hypertrophic / Other Abnormal Scarring (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	480	0.4% (0.0%, 1.0%)	3	960	0.3% (0.0%, 0.7%)
6 Months	6	469	1.2% (0.3%, 2.2%)	9	939	0.9% (0.3%, 1.5%)
1 Year	8	456	1.7% (0.5%, 2.8%)	12	913	1.3% (0.5%, 2.0%)
2 Years	11	425	2.3% (1.0%, 3.7%)	17	851	1.8% (1.0%, 2.7%)
3 Years	11	304	2.3% (1.0%, 3.7%)	17	609	1.8% (1.0%, 2.7%)

CORE STUDY - AUGMENTATION

Table 105B: Risk of First Occurrence of Hypertrophic / Other Abnormal Scarring (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	480	0.4% (0.0%, 1.0%)	3	960	0.3% (0.0%, 0.7%)
6 Months	17	459	3.5% (1.9%, 5.2%)	27	923	2.8% (1.8%, 3.9%)
1 Year	28	437	5.9% (3.8%, 8.0%)	47	880	4.9% (3.6%, 6.3%)
2 Years	36	401	7.6% (5.2%,10.0%)	61	809	6.5% (4.9%, 8.1%)
3 Years	38	283	8.1% (5.7%,10.6%)	65	573	7.0% (5.4%, 8.6%)

CORE STUDY - AUGMENTATION

Table 106A: Incidence and Prevalence of Hypertrophic / Other Abnormal Scarring
(>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.4%)	2 (0.4%)	493	3 (0.3%)	3 (0.3%)	985
6 Months	4 (0.8%)	6 (1.2%)	482	6 (0.6%)	9 (0.9%)	963
1 Year	2 (0.4%)	7 (1.5%)	475	3 (0.3%)	11 (1.2%)	948
2 Years	3 (0.6%)	8 (1.7%)	464	5 (0.5%)	13 (1.4%)	925
3 Years	0 (0.0%)	3 (0.7%)	435	0 (0.0%)	4 (0.5%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 106B: Incidence and Prevalence of Hypertrophic / Other Abnormal Scarring
(All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.4%)	2 (0.4%)	493	3 (0.3%)	3 (0.3%)	985
6 Months	15 (3.1%)	17 (3.5%)	482	24 (2.5%)	27 (2.8%)	963
1 Year	11 (2.3%)	24 (5.1%)	475	20 (2.1%)	40 (4.2%)	948
2 Years	8 (1.7%)	23 (5.0%)	464	14 (1.5%)	39 (4.2%)	925
3 Years	2 (0.5%)	14 (3.2%)	435	4 (0.5%)	26 (3.0%)	866

CORE STUDY - AUGMENTATION

Table 107A: Time to Resolution of Hypertrophic / Other Abnormal Scarring
(>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 2)	
Minimum	679
Median	783
Mean	783
Maximum	887
Resolved - Time To Resolution (N = 9)	
Minimum	67
Median	186
Mean	211
Maximum	595
Combined - Time To Resolution (N = 11)	
Minimum	67
Median	212
Mean	315
Maximum	887

CORE STUDY - AUGMENTATION

Table 107B: Time to Resolution of Hypertrophic / Other Abnormal Scarring
(All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 12)	
Minimum	1
Median	626
Mean	564
Maximum	1096
Resolved - Time To Resolution (N = 26)	
Minimum	1
Median	178
Mean	209
Maximum	959
Combined - Time To Resolution (N = 38)	
Minimum	1
Median	197
Mean	321
Maximum	1096

CORE STUDY - AUGMENTATION

Table 108A: Distribution of Hypertrophic / Other Abnormal Scarring
Resolution Status (>= Moderate Severity)

Resolution Status	By Patient	
	n	%(N = 11)
Not Yet Resolved		
Undergoing Treatment	2	18.2%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	2	18.2%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	4	36.4%
With Non-Surgical Treatment	4	36.4%
Without Treatment	1	9.1%
Total	9	81.8%

Attachment 2

CORE STUDY - AUGMENTATION

Table 108B: Distribution of Hypertrophic / Other Abnormal Scarring Resolution Status (All Severity Levels)

Resolution Status	By Patient n	By Patient %(N = 38)
Not Yet Resolved		
Undergoing Treatment	9	23.7%
Treatment Not Possible	0	0.0%
Refused Treatment	3	7.9%
Total	12	31.6%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	4	10.5%
With Non-Surgical Treatment	14	36.8%
Without Treatment	8	21.1%
Total	26	68.4%

CORE STUDY - AUGMENTATION

Table 109A: Risk of First Occurrence of Other Nipple Related Observation (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	480	0.4% (0.0%, 1.0%)	3	960	0.3% (0.0%, 0.7%)
6 Months	5	470	1.0% (0.1%, 1.9%)	7	941	0.7% (0.2%, 1.3%)
1 Year	5	459	1.0% (0.1%, 1.9%)	7	918	0.7% (0.2%, 1.3%)
2 Years	6	429	1.3% (0.3%, 2.3%)	9	857	1.0% (0.3%, 1.6%)
3 Years	6	308	1.3% (0.3%, 2.3%)	9	615	1.0% (0.3%, 1.6%)

CORE STUDY - AUGMENTATION

Table 109B: Risk of First Occurrence of Other Nipple Related Observation (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	4	479	0.8% (0.0%, 1.6%)	6	959	0.6% (0.1%, 1.1%)
6 Months	9	467	1.9% (0.7%, 3.1%)	14	936	1.5% (0.7%, 2.2%)
1 Year	10	455	2.1% (0.8%, 3.3%)	16	911	1.7% (0.9%, 2.5%)
2 Years	12	424	2.5% (1.1%, 3.9%)	20	848	2.1% (1.2%, 3.0%)
3 Years	13	304	2.8% (1.3%, 4.2%)	21	608	2.2% (1.3%, 3.2%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 110A: Incidence and Prevalence of Other Nipple Related Observation
(>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.4%)	2 (0.4%)	493	3 (0.3%)	3 (0.3%)	985
6 Months	3 (0.6%)	5 (1.0%)	482	4 (0.4%)	7 (0.7%)	963
1 Year	0 (0.0%)	4 (0.8%)	475	0 (0.0%)	6 (0.6%)	948
2 Years	1 (0.2%)	3 (0.6%)	464	2 (0.2%)	5 (0.5%)	925
3 Years	0 (0.0%)	2 (0.5%)	435	0 (0.0%)	2 (0.2%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 110B: Incidence and Prevalence of Other Nipple Related Observation
(All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	4 (0.8%)	4 (0.8%)	493	6 (0.6%)	6 (0.6%)	985
6 Months	5 (1.0%)	8 (1.7%)	482	8 (0.8%)	12 (1.2%)	963
1 Year	1 (0.2%)	7 (1.5%)	475	2 (0.2%)	11 (1.2%)	948
2 Years	2 (0.4%)	7 (1.5%)	464	4 (0.4%)	12 (1.3%)	925
3 Years	1 (0.2%)	6 (1.4%)	435	1 (.0.1%)	7 (0.8%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 111A: Time to Resolution of Other Nipple Related Observation
(>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	135
Median	135
Mean	135
Maximum	135
Resolved - Time To Resolution (N = 5)	
Minimum	143
Median	182
Mean	205
Maximum	351
Combined - Time To Resolution (N = 6)	
Minimum	135
Median	172
Mean	193
Maximum	351

CORE STUDY - AUGMENTATION

Table 111B: Time to Resolution of Other Nipple Related Observation
(All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 5)	
Minimum	1
Median	135
Mean	174
Maximum	371
Resolved - Time To Resolution (N = 8)	
Minimum	136
Median	183
Mean	256
Maximum	707
Combined - Time To Resolution (N = 13)	
Minimum	1
Median	182
Mean	225
Maximum	707

CORE STUDY - AUGMENTATION

Table 112A: Distribution of Other Nipple Related Observation
Resolution Status (>= Moderate Severity)

Resolution Status	By Patient	
	n	%(N = 6)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	1	16.7%
Total	1	16.7%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	3	50.0%
Without Treatment	2	33.3%
Total	5	83.3%

Attachment 2

CORE STUDY - AUGMENTATION

Table 112B: Distribution of Other Nipple Related Observation Resolution Status (All Severity Levels)

Resolution Status	By Patient n	By Patient %(N = 13)
Not Yet Resolved		
Undergoing Treatment	2	15.4%
Treatment Not Possible	0	0.0%
Refused Treatment	3	23.1%
Total	5	38.5%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	3	23.1%
Without Treatment	5	38.5%
Total	8	61.5%

CORE STUDY - AUGMENTATION

Table 113: Risk of First Occurrence of Pneumothorax (All Severity Levels)

	By Patient				By Implant			
	Number Affected	Number Remaining		Cumulative Risk	Number Affected	Number Remaining		Cumulative Risk
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	482	0.0%	--	0	963	0.0%	--
6 Months	0	475	0.0%	--	0	948	0.0%	--
1 Year	0	464	0.0%	--	0	925	0.0%	--
2 Years	0	435	0.0%	--	0	866	0.0%	--
3 Years	0	312	0.0%	--	0	621	0.0%	--

CORE STUDY - AUGMENTATION

Table 114: Incidence and Prevalence of Pneumothorax (All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	482	0 (0.0%)	0 (0.0%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 115: Time to Resolution of Pneumothorax (>= Moderate Severity)

THERE WAS NO PNEUMOTHORAX OBSERVED AMONG AUGMENTATION PATIENTS

CORE STUDY - AUGMENTATION

Table 116: Distribution of Pneumothorax Resolution Status
(All Severity Levels)

THERE WAS NO PNEUMOTHORAX OBSERVED AMONG AUGMENTATION PATIENTS

CORE STUDY - AUGMENTATION

Table 117A: Risk of First Occurrence of Ptosis (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	482	0.0% --	0	963	0.0% --
6 Months	1	475	0.2% (0.0%, 0.6%)	2	948	0.2% (0.0%, 0.5%)
1 Year	3	462	0.6% (0.0%, 1.3%)	6	921	0.6% (0.1%, 1.1%)
2 Years	6	431	1.3% (0.3%, 2.3%)	12	858	1.3% (0.6%, 2.0%)
3 Years	8	307	1.8% (0.6%, 3.1%)	15	612	1.7% (0.8%, 2.5%)

CORE STUDY - AUGMENTATION

Table 117B: Risk of First Occurrence of Ptosis (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	480	0.4% (0.0%, 1.0%)	3	960	0.3% (0.0%, 0.7%)
6 Months	4	472	0.8% (0.0%, 1.6%)	7	943	0.7% (0.2%, 1.3%)
1 Year	6	459	1.3% (0.3%, 2.2%)	11	916	1.2% (0.5%, 1.8%)
2 Years	13	425	2.8% (1.3%, 4.3%)	25	847	2.7% (1.7%, 3.7%)
3 Years	15	304	3.3% (1.7%, 5.0%)	28	607	3.1% (2.0%, 4.2%)

CORE STUDY - AUGMENTATION

Table 118A: Incidence and Prevalence of Ptosis (>= Moderate Severity)

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	1 (0.2%)	1 (0.2%)	482	2 (0.2%)	2 (0.2%)	963
1 Year	2 (0.4%)	2 (0.4%)	475	4 (0.4%)	4 (0.4%)	948
2 Years	3 (0.6%)	5 (1.1%)	464	6 (0.6%)	10 (1.1%)	925
3 Years	2 (0.5%)	3 (0.7%)	435	3 (0.3%)	5 (0.6%)	866

CORE STUDY - AUGMENTATION

Table 118B: Incidence and Prevalence of Ptosis (All Severity Levels)

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.4%)	2 (0.4%)	493	3 (0.3%)	3 (0.3%)	985
6 Months	2 (0.4%)	4 (0.8%)	482	4 (0.4%)	7 (0.7%)	963
1 Year	2 (0.4%)	4 (0.8%)	475	4 (0.4%)	7 (0.7%)	948
2 Years	7 (1.5%)	11 (2.4%)	464	14 (1.5%)	21 (2.3%)	925
3 Years	2 (0.5%)	8 (1.8%)	435	3 (0.3%)	14 (1.6%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 119A: Time to Resolution of Ptosis (All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 3)	
Minimum	42
Median	406
Mean	442
Maximum	878
Resolved - Time To Resolution (N = 5)	
Minimum	1
Median	34
Mean	53
Maximum	190
Combined - Time To Resolution (N = 8)	
Minimum	1
Median	41
Mean	199
Maximum	878

CORE STUDY - AUGMENTATION

Table 119B: Time to Resolution of Ptosis (All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 8)	
Minimum	1
Median	386
Mean	407
Maximum	1101
Resolved - Time To Resolution (N = 7)	
Minimum	1
Median	34
Mean	91
Maximum	368
Combined - Time To Resolution (N = 15)	
Minimum	1
Median	56
Mean	259
Maximum	1101

Attachment 2

CORE STUDY - AUGMENTATION

Table 120A: Distribution of Ptosis Resolution Status (>= Moderate Severity)

Resolution Status	By Patient n	By Patient %(N = 8)
Not Yet Resolved		
Undergoing Treatment	2	25.0%
Treatment Not Possible	0	0.0%
Refused Treatment	1	12.5%
Total	3	37.5%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	3	37.5%
With Non-Surgical Treatment	2	25.0%
Without Treatment	0	0.0%
Total	5	62.5%

CORE STUDY - AUGMENTATION

Table 120B: Distribution of Ptosis Resolution Status (All Severity Levels)

Resolution Status	By Patient	
	n	%(N = 15)
Not Yet Resolved		
Undergoing Treatment	5	33.3%
Treatment Not Possible	0	0.0%
Refused Treatment	3	20.0%
Total	8	53.3%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	3	20.0%
With Non-Surgical Treatment	2	13.3%
Without Treatment	2	13.3%
Total	7	46.7%

CORE STUDY - AUGMENTATION

Table 121A: Risk of First Occurrence of Redness (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	4	478	0.8% (0.0%, 1.6%)	6	957	0.6% (0.1%, 1.1%)
6 Months	4	471	0.8% (0.0%, 1.6%)	6	942	0.6% (0.1%, 1.1%)
1 Year	4	460	0.8% (0.0%, 1.6%)	6	919	0.6% (0.1%, 1.1%)
2 Years	4	431	0.8% (0.0%, 1.6%)	6	860	0.6% (0.1%, 1.1%)
3 Years	5	307	1.1% (0.1%, 2.1%)	7	614	0.8% (0.2%, 1.4%)

CORE STUDY - AUGMENTATION

Table 121B: Risk of First Occurrence of Redness (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	8	474	1.6% (0.5%, 2.8%)	14	949	1.4% (0.7%, 2.2%)
6 Months	10	466	2.1% (0.8%, 3.3%)	16	933	1.7% (0.8%, 2.5%)
1 Year	10	455	2.1% (0.8%, 3.3%)	16	910	1.7% (0.8%, 2.5%)
2 Years	10	426	2.1% (0.8%, 3.3%)	16	851	1.7% (0.8%, 2.5%)
3 Years	12	303	2.6% (1.1%, 4.1%)	18	607	1.9% (1.0%, 2.8%)

CORE STUDY - AUGMENTATION

Table 122A: Incidence and Prevalence of Redness (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	4 (0.8%)	4 (0.8%)	493	6 (0.6%)	6 (0.6%)	985
6 Months	0 (0.0%)	1 (0.2%)	482	0 (0.0%)	2 (0.2%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	1 (0.2%)	1 (0.2%)	435	1 (0.1%)	1 (0.1%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 122B: Incidence and Prevalence of Redness (All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	8 (1.6%)	8 (1.6%)	493	14 (1.4%)	14 (1.4%)	985
6 Months	2 (0.4%)	3 (0.6%)	482	2 (0.2%)	4 (0.4%)	963
1 Year	0 (0.0%)	1 (0.2%)	475	0 (0.0%)	1 (0.1%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	2 (0.5%)	2 (0.5%)	435	2 (0.2%)	2 (0.2%)	866

CORE STUDY - AUGMENTATION

Table 123A: Time to Resolution of Redness (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 5)	
Minimum	7
Median	8
Mean	19
Maximum	63
Combined - Time To Resolution (N = 5)	
Minimum	7
Median	8
Mean	19
Maximum	63

CORE STUDY - AUGMENTATION

Table 123B: Time to Resolution of Redness (All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	4
Median	4
Mean	4
Maximum	4
Resolved - Time To Resolution (N = 11)	
Minimum	1
Median	8
Mean	51
Maximum	355
Combined - Time To Resolution (N = 12)	
Minimum	1
Median	8
Mean	47
Maximum	355

CORE STUDY - AUGMENTATION

Table 124A: Distribution of Redness Resolution Status
(>= Moderate Severity)

	By Patient	
Resolution Status	n	%(N = 5)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	4	80.0%
Without Treatment	1	20.0%
Total	5	100.0%

Attachment 2

CORE STUDY - AUGMENTATION

Table 124B: Distribution of Redness Resolution Status (All Severity Levels)

	By Patient	
Resolution Status	n	%(N = 12)
Not Yet Resolved		
Undergoing Treatment	1	8.3%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	8.3%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	6	50.0%
Without Treatment	5	41.7%
Total	11	91.7%

CORE STUDY - AUGMENTATION

Table 125A: Risk of First Occurrence of Seroma / Fluid Accumulation (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	1	481	0.2% (0.0%, 0.6%)	1	962	0.1% (0.0%, 0.3%)
6 Months	4	471	0.8% (0.0%, 1.6%)	5	943	0.5% (0.1%, 1.0%)
1 Year	5	459	1.0% (0.1%, 2.0%)	6	919	0.6% (0.1%, 1.1%)
2 Years	5	431	1.0% (0.1%, 2.0%)	6	862	0.6% (0.1%, 1.1%)
3 Years	5	310	1.0% (0.1%, 2.0%)	6	619	0.6% (0.1%, 1.1%)

CORE STUDY - AUGMENTATION

Table 125B: Risk of First Occurrence of Seroma / Fluid Accumulation (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	6	476	1.2% (0.3%, 2.2%)	10	953	1.0% (0.4%, 1.7%)
6 Months	11	465	2.3% (0.9%, 3.6%)	16	933	1.7% (0.8%, 2.5%)
1 Year	13	452	2.7% (1.3%, 4.1%)	18	908	1.9% (1.0%, 2.7%)
2 Years	13	425	2.7% (1.3%, 4.1%)	18	852	1.9% (1.0%, 2.7%)
3 Years	13	306	2.7% (1.3%, 4.1%)	18	613	1.9% (1.0%, 2.7%)

CORE STUDY - AUGMENTATION

Table 126A: Incidence and Prevalence of Seroma / Fluid Accumulation (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.2%)	1 (0.2%)	493	1 (0.1%)	1 (0.1%)	985
6 Months	3 (0.6%)	4 (0.8%)	482	4 (0.4%)	5 (0.5%)	963
1 Year	1 (0.2%)	1 (0.2%)	475	1 (0.1%)	1 (0.1%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 126B: Incidence and Prevalence of Seroma / Fluid Accumulation (All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	6 (1.2%)	6 (1.2%)	493	10 (1.0%)	10 (1.0%)	985
6 Months	5 (1.0%)	8 (1.7%)	482	6 (0.6%)	10 (1.0%)	963
1 Year	2 (0.4%)	2 (0.4%)	475	2 (0.2%)	2 (0.2%)	948
2 Years	0 (0.0%)	1 (0.2%)	464	0 (0.0%)	1 (0.1%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 127A: Time to Resolution of Seroma / Fluid Accumulation
(>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 5)	
Minimum	1
Median	23
Mean	33
Maximum	84
Combined - Time To Resolution (N = 5)	
Minimum	1
Median	23
Mean	33
Maximum	84

CORE STUDY - AUGMENTATION

Table 127B: Time to Resolution of Seroma / Fluid Accumulation
(All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 2)	
Minimum	4
Median	65
Mean	65
Maximum	126
Resolved - Time To Resolution (N = 11)	
Minimum	1
Median	21
Mean	23
Maximum	84
Combined - Time To Resolution (N = 13)	
Minimum	1
Median	21
Mean	30
Maximum	126

CORE STUDY - AUGMENTATION

Table 128A: Distribution of Seroma / Fluid Accumulation Resolution Status
(>= Moderate Severity)

Resolution Status	By Patient n	By Patient %(N = 5)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	3	60.0%
Without Treatment	2	40.0%
Total	5	100.0%

Attachment 2

CORE STUDY - AUGMENTATION

Table 128B: Distribution of Seroma / Fluid Accumulation Resolution Status
(All Severity Levels)

	By Patient	
Resolution Status	n	%(N = 13)
Not Yet Resolved		
Undergoing Treatment	2	15.4%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	2	15.4%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	15.4%
Without Treatment	9	69.2%
Total	11	84.6%

CORE STUDY - AUGMENTATION

Table 129: Risk of First Occurrence of Skin Hypersensitivity

N/A: SKIN HYPERSENSITIVITY HAS BEEN COMBINED WITH LOSS OF SKIN SENSATION AND SKIN PARESTHESIA

CORE STUDY - AUGMENTATION

Table 130: Incidence and Prevalence of Skin Hypersensitivity

N/A: SKIN HYPERSENSITIVITY HAS BEEN COMBINED WITH LOSS OF SKIN SENSATION AND SKIN PARESTHESIA

CORE STUDY - AUGMENTATION

Table 131: Time to Resolution of Skin Hypersensitivity

N/A: SKIN HYPERSENSITIVITY HAS BEEN COMBINED WITH LOSS OF SKIN SENSATION AND SKIN PARESTHESIA

CORE STUDY - AUGMENTATION

Table 132: Distribution of Skin Hypersensitivity Resolution Status

N/A: SKIN HYPERSENSITIVITY HAS BEEN COMBINED WITH LOSS OF SKIN SENSATION AND SKIN PARESTHESIA

CORE STUDY - AUGMENTATION

Table 133: Risk of First Occurrence of Skin Hypersensitivity / Paresthesia / Loss of Skin Sensation

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	7	475	1.4% (0.4%, 2.5%)	11	952	1.1% (0.5%, 1.8%)
6 Months	7	468	1.4% (0.4%, 2.5%)	11	937	1.1% (0.5%, 1.8%)
1 Year	8	456	1.7% (0.5%, 2.8%)	13	912	1.4% (0.6%, 2.1%)
2 Years	8	428	1.7% (0.5%, 2.8%)	13	854	1.4% (0.6%, 2.1%)
3 Years	8	306	1.7% (0.5%, 2.8%)	13	610	1.4% (0.6%, 2.1%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 134: Incidence and Prevalence of Skin Hypersensitivity / Paresthesia / Loss of Skin Sensation

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	7 (1.4%)	7 (1.4%)	493	11 (1.1%)	11 (1.1%)	985
6 Months	0 (0.0%)	7 (1.5%)	482	0 (0.0%)	11 (1.1%)	963
1 Year	1 (0.2%)	3 (0.6%)	475	2 (0.2%)	5 (0.5%)	948
2 Years	0 (0.0%)	1 (0.2%)	464	0 (0.0%)	1 (0.1%)	925
3 Years	0 (0.0%)	1 (0.2%)	435	0 (0.0%)	1 (0.1%)	866

CORE STUDY - AUGMENTATION

Table 135: Time to Resolution of Skin Hypersensitivity / Paresthesia / Loss of Skin Sensation

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	739
Median	739
Mean	739
Maximum	739
Resolved - Time To Resolution (N = 7)	
Minimum	1
Median	42
Mean	61
Maximum	201
Combined - Time To Resolution (N = 8)	
Minimum	1
Median	50
Mean	146
Maximum	739

CORE STUDY - AUGMENTATION

Table 136: Distribution of Skin Hypersensitivity / Paresthesia / Loss of Skin Sensation Resolution Status

Resolution Status	By Patient n	By Patient %(N = 8)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	1	12.5%
Refused Treatment	0	0.0%
Total	1	12.5%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	1	12.5%
Without Treatment	6	75.0%
Total	7	87.5%

CORE STUDY - AUGMENTATION

Table 137A: Risk of First Occurrence of Skin Rash (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	5	477	1.0% (0.1%, 1.9%)	10	953	1.0% (0.4%, 1.7%)
6 Months	8	467	1.7% (0.5%, 2.8%)	15	934	1.6% (0.8%, 2.3%)
1 Year	8	456	1.7% (0.5%, 2.8%)	15	911	1.6% (0.8%, 2.3%)
2 Years	8	428	1.7% (0.5%, 2.8%)	15	854	1.6% (0.8%, 2.3%)
3 Years	8	308	1.7% (0.5%, 2.8%)	15	615	1.6% (0.8%, 2.3%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 137B: Risk of First Occurrence of Skin Rash (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	11	472	2.3% (0.9%, 3.6%)	20	945	2.1% (1.2%, 2.9%)
6 Months	14	462	2.9% (1.4%, 4.4%)	25	926	2.6% (1.6%, 3.6%)
1 Year	15	450	3.1% (1.6%, 4.6%)	27	901	2.8% (1.7%, 3.8%)
2 Years	15	423	3.1% (1.6%, 4.6%)	27	846	2.8% (1.7%, 3.8%)
3 Years	15	305	3.1% (1.6%, 4.6%)	27	610	2.8% (1.7%, 3.8%)

CORE STUDY - AUGMENTATION

Table 138A: Incidence and Prevalence of Skin Rash (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	5 (1.0%)	5 (1.0%)	493	10 (1.0%)	10 (1.0%)	985
6 Months	3 (0.6%)	5 (1.0%)	482	5 (0.5%)	9 (0.9%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 138B: Incidence and Prevalence of Skin Rash (All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	11 (2.2%)	11 (2.2%)	493	20 (2.0%)	20 (2.0%)	985
6 Months	3 (0.6%)	7 (1.5%)	482	5 (0.5%)	12 (1.2%)	963
1 Year	1 (0.2%)	1 (0.2%)	475	2 (0.2%)	2 (0.2%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 139A: Time to Resolution of Skin Rash (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 8)*	
Minimum	1
Median	16
Mean	25
Maximum	74
Combined - Time To Resolution (N = 8)	
Minimum	1
Median	16
Mean	25
Maximum	74

* Includes 1 occurrence of Skin Rash that was resolved after explantation of the patient's primary study device.

Attachment 2

CORE STUDY - AUGMENTATION

Table 139B: Time to Resolution of Skin Rash (All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 15)*	
Minimum	1
Median	11
Mean	28
Maximum	169
Combined - Time To Resolution (N = 15)	
Minimum	1
Median	11
Mean	28
Maximum	169

* Includes 1 occurrence of Skin Rash that was resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 140A: Distribution of Skin Rash Resolution Status
(>= Moderate Severity)

Resolution Status	By Patient n	By Patient %(N = 8)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved*		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	8	100.0%
Without Treatment	0	0.0%
Total	8	100.0%

* Includes 1 occurrence of Skin Rash that was resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 140B: Distribution of Skin Rash Resolution Status
(All Severity Levels)

	By Patient	
Resolution Status	n	%(N = 15)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved*		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	14	93.3%
Without Treatment	1	6.7%
Total	15	100.0%

* Includes 1 occurrence of Skin Rash that was resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 141A: Risk of First Occurrence of Swelling (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	29	454	5.9% (3.8%, 8.0%)	49	916	5.0% (3.6%, 6.4%)
6 Months	30	447	6.1% (4.0%, 8.2%)	50	902	5.1% (3.7%, 6.5%)
1 Year	33	433	6.8% (4.5%, 9.0%)	55	874	5.6% (4.2%, 7.1%)
2 Years	33	408	6.8% (4.5%, 9.0%)	55	822	5.6% (4.2%, 7.1%)
3 Years	33	295	6.8% (4.5%, 9.0%)	55	594	5.6% (4.2%, 7.1%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 141B: Risk of First Occurrence of Swelling (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	108	375	22.0% (18.4%,25.7%)	209	756	21.3% (18.8%,23.9%)
6 Months	110	370	22.4% (18.7%,26.1%)	211	747	21.5% (19.0%,24.1%)
1 Year	114	355	23.3% (19.5%,27.0%)	217	718	22.2% (19.6%,24.8%)
2 Years	114	336	23.3% (19.5%,27.0%)	217	679	22.2% (19.6%,24.8%)
3 Years	114	248	23.3% (19.5%,27.0%)	217	500	22.2% (19.6%,24.8%)

CORE STUDY - AUGMENTATION

Table 142A: Incidence and Prevalence of Swelling (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	29 (5.9%)	29 (5.9%)	493	49 (5.0%)	49 (5.0%)	985
6 Months	1 (0.2%)	14 (2.9%)	482	1 (0.1%)	21 (2.2%)	963
1 Year	3 (0.6%)	6 (1.3%)	475	5 (0.5%)	9 (0.9%)	948
2 Years	0 (0.0%)	2 (0.4%)	464	0 (0.0%)	2 (0.2%)	925
3 Years	0 (0.0%)	2 (0.5%)	435	0 (0.0%)	2 (0.2%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 142B: Incidence and Prevalence of Swelling (All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	108 (21.9%)	108 (21.9%)	493	209 (21.2%)	209 (21.2%)	985
6 Months	2 (0.4%)	32 (6.6%)	482	2 (0.2%)	62 (6.4%)	963
1 Year	4 (0.8%)	10 (2.1%)	475	6 (0.6%)	18 (1.9%)	948
2 Years	0 (0.0%)	6 (1.3%)	464	0 (0.0%)	11 (1.2%)	925
3 Years	0 (0.0%)	4 (0.9%)	435	0 (0.0%)	8 (0.9%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 143A: Time to Resolution of Swelling (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 2)	
Minimum	1093
Median	1096
Mean	1096
Maximum	1099
Resolved - Time To Resolution (N = 31)	
Minimum	1
Median	18
Mean	33
Maximum	196
Combined - Time To Resolution (N = 33)	
Minimum	1
Median	21
Mean	98
Maximum	1099

CORE STUDY - AUGMENTATION

Table 143B: Time to Resolution of Swelling (All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 4)	
Minimum	740
Median	1096
Mean	1020
Maximum	1146
Resolved - Time To Resolution (N = 110)	
Minimum	1
Median	6
Mean	22
Maximum	380
Combined - Time To Resolution (N = 114)	
Minimum	1
Median	7
Mean	57
Maximum	1146

CORE STUDY - AUGMENTATION

Table 144A: Distribution of Swelling Resolution Status
(>= Moderate Severity)

Resolution Status	By Patient	
	n	%(N = 33)
Not Yet Resolved		
Undergoing Treatment	2	6.1%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	2	6.1%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	6	18.2%
Without Treatment	25	75.8%
Total	31	93.9%

CORE STUDY - AUGMENTATION

Table 144B: Distribution of Swelling Resolution Status
(All Severity Levels)

Resolution Status	By Patient n	By Patient %(N =114)
Not Yet Resolved		
Undergoing Treatment	4	3.5%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	4	3.5%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	10	8.8%
Without Treatment	100	87.7%
Total	110	96.5%

CORE STUDY - AUGMENTATION

Table 145A: Risk of First Occurrence of Tissue/Skin Necrosis (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	1	481	0.2% (0.0%, 0.6%)	1	962	0.1% (0.0%, 0.3%)
6 Months	1	474	0.2% (0.0%, 0.6%)	1	947	0.1% (0.0%, 0.3%)
1 Year	1	463	0.2% (0.0%, 0.6%)	1	924	0.1% (0.0%, 0.3%)
2 Years	1	434	0.2% (0.0%, 0.6%)	1	865	0.1% (0.0%, 0.3%)
3 Years	1	311	0.2% (0.0%, 0.6%)	1	620	0.1% (0.0%, 0.3%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 145B: Risk of First Occurrence of Tissue/Skin Necrosis (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	1	481	0.2% (0.0%, 0.6%)	1	962	0.1% (0.0%, 0.3%)
6 Months	1	474	0.2% (0.0%, 0.6%)	1	947	0.1% (0.0%, 0.3%)
1 Year	1	463	0.2% (0.0%, 0.6%)	1	924	0.1% (0.0%, 0.3%)
2 Years	1	434	0.2% (0.0%, 0.6%)	1	865	0.1% (0.0%, 0.3%)
3 Years	1	311	0.2% (0.0%, 0.6%)	1	620	0.1% (0.0%, 0.3%)

CORE STUDY - AUGMENTATION

Table 146A: Incidence and Prevalence of Tissue/Skin Necrosis (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.2%)	1 (0.2%)	493	1 (0.1%)	1 (0.1%)	985
6 Months	0 (0.0%)	1 (0.2%)	482	0 (0.0%)	1 (0.1%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 146B: Incidence and Prevalence of Tissue/Skin Necrosis (All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.2%)	1 (0.2%)	493	1 (0.1%)	1 (0.1%)	985
6 Months	0 (0.0%)	1 (0.2%)	482	0 (0.0%)	1 (0.1%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

CORE STUDY - AUGMENTATION

Table 147A: Time to Resolution of Tissue / Skin Necrosis
(>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 1)	
Minimum	29
Median	29
Mean	29
Maximum	29
Combined - Time To Resolution (N = 1)	
Minimum	29
Median	29
Mean	29
Maximum	29

CORE STUDY - AUGMENTATION

Table 147B: Time to Resolution of Tissue / Skin Necrosis (All Severity Levels)

	Measurement in Days
Resolution	By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 1)	
Minimum	29
Median	29
Mean	29
Maximum	29
Combined - Time To Resolution (N = 1)	
Minimum	29
Median	29
Mean	29
Maximum	29

CORE STUDY - AUGMENTATION

Table 148A: Distribution of Tissue / Skin Necrosis Resolution Status
(>= Moderate Severity)

Resolution Status	By Patient n	By Patient %(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	1	100.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	1	100.0%

CORE STUDY - AUGMENTATION

Table 148B: Distribution of Tissue / Skin Necrosis Resolution Status
(All Severity Levels)

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	1	100.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	1	100.0%

CORE STUDY - AUGMENTATION

Table 149: Risk of First Occurrence of Wrinkling/Rippling (>= Moderate Severity)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	1	481	0.2% (0.0%, 0.6%)	1	962	0.1% (0.0%, 0.3%)
6 Months	1	474	0.2% (0.0%, 0.6%)	1	947	0.1% (0.0%, 0.3%)
1 Year	2	462	0.4% (0.0%, 1.0%)	3	922	0.3% (0.0%, 0.7%)
2 Years	2	433	0.4% (0.0%, 1.0%)	3	863	0.3% (0.0%, 0.7%)
3 Years	3	310	0.7% (0.0%, 1.6%)	4	618	0.5% (0.0%, 0.9%)

CORE STUDY - AUGMENTATION

Table 150: Incidence and Prevalence of Wrinkling/Rippling (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.2%)	1 (0.2%)	493	1 (0.1%)	1 (0.1%)	985
6 Months	0 (0.0%)	1 (0.2%)	482	0 (0.0%)	1 (0.1%)	963
1 Year	1 (0.2%)	2 (0.4%)	475	2 (0.2%)	3 (0.3%)	948
2 Years	0 (0.0%)	1 (0.2%)	464	0 (0.0%)	1 (0.1%)	925
3 Years	1 (0.2%)	2 (0.5%)	435	1 (0.1%)	2 (0.2%)	866

Attachment 2

CORE STUDY - AUGMENTATION

Table 151: Time to Resolution of Wrinkling / Rippling (>= Moderate Severity)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 2)	
Minimum	1
Median	736
Mean	736
Maximum	1471
Resolved - Time To Resolution (N = 1)	
Minimum	106
Median	106
Mean	106
Maximum	106
Combined - Time To Resolution (N = 3)	
Minimum	1
Median	106
Mean	526
Maximum	1471

CORE STUDY - AUGMENTATION

Table 152: Distribution of Wrinkling / Rippling Resolution Status
(>= Moderate Severity)

	By Patient	
Resolution Status	n	%(N = 3)
Not Yet Resolved		
Undergoing Treatment	2	66.7%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	2	66.7%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	1	33.3%
Without Treatment	0	0.0%
Total	1	33.3%

CORE STUDY - AUGMENTATION

Table 153A: Risk of First Occurrence of Other Complications (>= Moderate Severity)

	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
Time	n	n	%	(95% CI)'	n	n	%	(95% CI)
4 Weeks	0	482	0.0%	--	0	963	0.0%	--
6 Months	0	475	0.0%	--	0	948	0.0%	--
1 Year	0	464	0.0%	--	0	925	0.0%	--
2 Years	0	435	0.0%	--	0	866	0.0%	--
3 Years	0	312	0.0%	--	0	621	0.0%	--

Attachment 2

CORE STUDY - AUGMENTATION

Table 153B: Risk of First Occurrence of Other Complications (All Severity Levels)

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	1	481	0.2% (0.0%, 0.6%)	2	961	0.2% (0.0%, 0.5%)
6 Months	1	474	0.2% (0.0%, 0.6%)	2	946	0.2% (0.0%, 0.5%)
1 Year	1	463	0.2% (0.0%, 0.6%)	2	923	0.2% (0.0%, 0.5%)
2 Years	1	434	0.2% (0.0%, 0.6%)	2	864	0.2% (0.0%, 0.5%)
3 Years	1	311	0.2% (0.0%, 0.6%)	2	619	0.2% (0.0%, 0.5%)

CORE STUDY - AUGMENTATION

Table 153B (Cont.): Risk of First Occurrence of Other Complications (All Severity Levels)

Other Complications Specified (N = 2)

Pt Seq#	Other Complications Specified
001*	MILD ALLERGIC REACTION TO COMPAZINE
001*	MILD ALLERGIC REACTION TO COMPAZINE

* Both the patient's left and right breasts experienced the same complication.

CORE STUDY - AUGMENTATION

Table 154A: Incidence and Prevalence of Other Complications (>= Moderate Severity)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	482	0 (0.0%)	0 (0.0%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

CORE STUDY - AUGMENTATION

Table 154B: Incidence and Prevalence of Other Complications (All Severity Levels)

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.2%)	1 (0.2%)	493	2 (0.2%)	2 (0.2%)	985
6 Months	0 (0.0%)	0 (0.0%)	482	0 (0.0%)	0 (0.0%)	963
1 Year	0 (0.0%)	0 (0.0%)	475	0 (0.0%)	0 (0.0%)	948
2 Years	0 (0.0%)	0 (0.0%)	464	0 (0.0%)	0 (0.0%)	925
3 Years	0 (0.0%)	0 (0.0%)	435	0 (0.0%)	0 (0.0%)	866

CORE STUDY - AUGMENTATION

Table 155A: Time to Resolution of Other Complications (>= Moderate Severity)

THERE WAS NO OTHER COMPLICATIONS OBSERVED AMONG AUGMENTATION PATIENTS

CORE STUDY - AUGMENTATION

Table 155B: Time to Resolution of Other Complications (All Severity Levels)

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Mean	.
Maximum	.
Resolved - Time To Resolution (N = 1)	
Minimum	1
Median	1
Mean	1
Maximum	1
Combined - Time To Resolution (N = 1)	
Minimum	1
Median	1
Mean	1
Maximum	1

Attachment 2

CORE STUDY - AUGMENTATION

Table 156A: Distribution of Other Complications Resolution Status
(>= Moderate Severity)

THERE WAS NO OTHER COMPLICATIONS OBSERVED AMONG AUGMENTATION PATIENTS

CORE STUDY - AUGMENTATION

Table 156B: Distribution of Other Complications Resolution Status
(All Severity Levels)

	By Patient	
Resolution Status	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	1	100.0%
Without Treatment	0	0.0%
Total	1	100.0%

CORE STUDY - AUGMENTATION

Table 157: Worst Case Severity Levels of Complications By Patient

		Severity Level* (Allowable Range 1 - 5)						
	Pts	Very Mild	Mild	Moderate	Severe	Very Severe	Descriptive Statistics	
Complication	N	%	%	%	%	%	Mean	SD
Asymmetry	40	30.0%	37.5%	20.0%	5.0%	7.5%	2.2	1.2
Breast Pain	67	25.4%	31.3%	23.9%	7.5%	11.9%	2.5	1.3
Bruising	45	26.7%	60.0%	11.1%	0.0%	2.2%	1.9	0.8
Capsule Calcification	1	0.0%	0.0%	0.0%	0.0%	100.0%	5.0	N/A**
Capsular Contracture***	55	12.7%	18.2%	49.1%	16.4%	3.6%	2.8	1.0
Delayed Wound Healing	14	21.4%	42.9%	35.7%	0.0%	0.0%	2.1	0.8
Fluid Accumulation	3	0.0%	33.3%	33.3%	33.3%	0.0%	3.0	1.0
Hematoma	5	20.0%	0.0%	60.0%	0.0%	20.0%	3.0	1.4
Hypertrophic Scarring	24	20.8%	45.8%	25.0%	8.3%	0.0%	2.2	0.9
Implant Extrusion	1	100.0%	0.0%	0.0%	0.0%	0.0%	1.0	N/A**
Implant Malposition	25	12.0%	32.0%	48.0%	4.0%	4.0%	2.6	0.9
Implant Palpability	12	50.0%	25.0%	25.0%	0.0%	0.0%	1.8	0.9
Infection	5	20.0%	60.0%	20.0%	0.0%	0.0%	2.0	0.7
Irritation	2	50.0%	50.0%	0.0%	0.0%	0.0%	1.5	0.7
Loss of Nipple Sensation	18	11.1%	5.6%	55.6%	16.7%	11.1%	3.1	1.1

CORE STUDY - AUGMENTATION

Table 157 (cont.): Worst Case Severity Levels of Complications By Patient

Complication	Pts	Severity Level* (Allowable Range 1 - 5) Very Mild	Mild	Moderate	Severe	Very Severe	Descriptive Statistics Mean	SD
	N	%	%	%	%	%		
Loss of Skin Sensation	11	27.3%	18.2%	45.5%	0.0%	9.1%	2.5	1.2
Lymphadenopathy	2	0.0%	50.0%	0.0%	50.0%	0.0%	3.0	1.4
Lymphedema	1	0.0%	0.0%	0.0%	0.0%	100.0%	5.0	N/A**
Nipple Hypersensitivity	9	33.3%	44.4%	11.1%	11.1%	0.0%	2.0	1.0
Nipple Paresthesia	4	25.0%	25.0%	25.0%	25.0%	0.0%	2.5	1.3
Other Abnormal Scarring	16	31.3%	43.8%	12.5%	6.3%	6.3%	2.1	1.1
Other Nipple Related Observation	13	30.8%	23.1%	38.5%	0.0%	7.7%	2.3	1.2
Ptosis	15	13.3%	33.3%	33.3%	6.7%	13.3%	2.7	1.2
Redness	12	16.7%	41.7%	33.3%	0.0%	8.3%	2.4	1.1
Seroma	11	36.4%	36.4%	9.1%	18.2%	0.0%	2.1	1.1
Skin Hypersensitivity	4	75.0%	25.0%	0.0%	0.0%	0.0%	1.3	0.5
Skin Paresthesia	2	0.0%	0.0%	50.0%	0.0%	50.0%	4.0	1.4
Skin Rash	15	20.0%	26.7%	40.0%	13.3%	0.0%	2.5	1.0
Swelling	114	20.2%	50.9%	23.7%	0.0%	5.3%	2.2	0.9
Tissue or Skin Necrosis	1	0.0%	0.0%	0.0%	100.0%	0.0%	4.0	N/A**
Wrinkling/Rippling	11	27.3%	45.5%	27.3%	0.0%	0.0%	2.0	0.8
Other Complications	1	0.0%	100.0%	0.0%	0.0%	0.0%	2.0	N/A**

CORE STUDY - AUGMENTATION

Table 157 (cont.): Worst Case Severity Levels of Complications By Patient

Complication	Pts	Severity Level* (Allowable Range 1 - 5) Very Mild	Mild	Moderate	Severe	Very Severe	Descriptive Statistics Mean	SD
	N	%	%	%	%	%		
Seroma / Fluid Accumulation	13	30.8%	30.8%	15.4%	23.1%	0.0%	2.3	1.2
Implant Palpability / Visibility	12	50.0%	25.0%	25.0%	0.0%	0.0%	1.8	0.9
Hypertrophic / Other Abnormal Scarring	38	23.7%	47.4%	21.1%	5.3%	2.6%	2.2	0.9
Nipple Hypersensitivity / Paresthesia / Loss of Nipple Sensation	31	19.4%	19.4%	38.7%	16.1%	6.5%	2.7	1.2
Skin Hypersensitivity / Paresthesia / Loss of Skin Sensation	17	35.3%	17.6%	35.3%	0.0%	11.8%	2.4	1.3

* Severity level ranged from 1 (very mild) to 5 (very severe).
** Standard deviation (SD) is N/A (Not Applicable) because N=1.
*** Included capsular contracture and breast firmness: Baker Grade I-IV for capsular contracture are indicated above as severity levels 1 to 4; severity for firmness ranged from 1 to 5.

Table 158: Implant Rupture

Implant Rupture	Implants n	Implants %(N = 987)
No Rupture	977	99.0%
Rupture Suspected Through:		
Explant	1	0.1%
MRI	6	0.6%
Reoperation	2	0.2%
Mammography	0	0.0%
Ultrasound	0	0.0%
Physician Exam	1	0.1%
	987	100.0%

Physician Exam – Symptom of Rupture	n	%(N = 1)
Lump/Mass/Nodules	0	0.0%
Implant Distortion	0	0.0%
Burning Sensation	0	0.0%
Softer Breast Texture	0	0.0%
Decreased Breast Size	0	0.0%
Pain/Tenderness	1	100.0%
Motor Vehicle Accident	1	100.0%
	2*	200.0%

* The sum of rupture symptoms listed may exceed the total number of implants identified as ruptured by physician exam because more than one symptom may be reported for the same implant.

Table 159: Suspected Implant Ruptures

Suspected Implant Ruptures	Implant Ruptures Identified	
	n	%(N = 10)
Confirmed Rupture by Explant	2	20.0%
False Report: Device Intact		
Explant Indicated Non-Rupture	1	10.0%
Mammography* Indicated Non-Rupture	3	30.0%
Ultrasound* Indicated Non-Rupture	1	10.0%
MRI* Indicated Non-Rupture	0	0.0%
Unconfirmed Rupture Status	3	30.0%
	10	100.0%

* Follow-up diagnostic test

CORE STUDY - AUGMENTATION

Table 160: Risk of First Occurrence of Implant Rupture

	By Patient				By Implant			
	Number Affected	Number Remaining		Cumulative Risk	Number Affected	Number Remaining		Cumulative Risk
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	482	0.0%	--	0	963	0.0%	--
6 Months	1	475	0.2%	(0.0%, 0.6%)	1	948	0.1%	(0.0%, 0.3%)
1 Year	2	463	0.4%	(0.0%, 1.0%)	2	924	0.2%	(0.0%, 0.5%)
2 Years	4	432	0.9%	(0.0%, 1.7%)	4	864	0.4%	(0.0%, 0.8%)
3 Years	5	308	1.2%	(0.1%, 2.2%)	5	618	0.6%	(0.1%, 1.1%)

CORE STUDY - AUGMENTATION

Table 161: Incidence and Prevalence of Implant Rupture

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0) %	0 (0.0%)	484	0 (0.0%)	0 (0.0%)	967
6 Months	1 (0.2) %	1 (0.2%)	473	1 (0.1%)	1 (0.1%)	945
1 Year	1 (0.2) %	1 (0.2%)	466	1 (0.1%)	1 (0.1%)	930
2 Years	2 (0.4) %	3 (0.7%)	455	2 (0.2%)	3 (0.3%)	907
3 Years	1 (0.2) %	3 (0.7%)	426	1 (0.1%)	3 (0.4%)	848

CORE STUDY - AUGMENTATION

Table 162: Distribution of Implant Rupture Resolution Status

Resolution Status	By Patient	
	n	%(N = 5)
Not Yet Resolved		
Undergoing Treatment	3	60.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	3	60.0%
Resolved		
With Reoperation and Explantation	2	40.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	2	40.0%

Attachment 2

CORE STUDY - AUGMENTATION

Table 163: Risk of First Occurrence of Reoperation

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	9	474	1.9% (0.7%, 3.0%)	9	956	0.9% (0.3%, 1.5%)
6 Months	29	453	6.0% (3.9%, 8.1%)	39	924	4.0% (2.8%, 5.3%)
1 Year	54	426	11.2% (8.4%,14.0%)	82	876	8.5% (6.8%,10.3%)
2 Years	82	378	17.2% (13.8%,20.6%)	128	789	13.5% (11.3%,15.6%)
3 Years	94	264	20.6% (16.8%,24.4%)	150	555	16.6% (14.1%,19.0%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 163A: Distribution of Resolution Status of Primary Reason for Reoperation

Resolution Status	By Patient n	By Patient %(N = 112)
Not Yet Resolved		
Undergoing Treatment	50	44.6%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	50	44.6%
Resolved		
With Reoperation and Explantation*	17	15.2%
With Reoperation Without Explantation*	40	35.7%
With Non-Surgical Treatment	3	2.7%
Without Treatment	2	1.8%
Total	62	55.4%

* Includes biopsy (n=1), size change (n=7), media anxiety (n=0) or unknown (n=1). Reoperations performed for these reasons do not require physicians to fill out a corresponding complication form, which documents the resolution status. Therefore, we assume they are resolved after reoperation, either with or without explantation.

Table 164: Number of Reoperations Per Patient

	Patients (N = 494)	
	n	%
No Reoperations	400	81.0%
At Least One Reoperation	94	19.0%
Total	494	100.0%

Breakdown of At Least One Reoperation	n	%(N = 94)
1 Reoperation	79	84.0%
2 Reoperations	12	12.8%
3 or More Reoperations	3	3.2%
Total	94	100.0%
Total Number of Reoperations	112*	

* Total number of reoperations is calculated as:
(79 * 1 reoperation) + (12 * 2 reoperations) + (3 * 3 reoperations) = 112 reoperations.

Table 165: Intraoperative Complications During Reoperation

Intraoperative Complications	Reoperations	
	n	%(N =112)
Yes	0	0.0%
No	107	95.5%
Unknown*	5	4.5%
	112	100.0%

* The implanting study physician did not perform the reoperation for these patients. No information regarding intraoperative complications was able to be obtained from the non-study surgeons who performed these reoperations.

Table 166: Primary* Reason for Reoperation

Reason	Patient Reoperations	
	n	%(N = 112)
Device Malfunction - Rupture	1	0.9%
Infection	0	0.0%
Capsular Contracture	35	31.3%
Extrusion	1	0.9%
Necrosis	1	0.9%
Healing Related		
Hematoma/Seroma	5	4.5%
Delayed Wound Healing	3	2.7%
Nipple Complications	1	0.9%
Pain	1	0.9%
Unsatisfactory Cosmetic Result		
Breast Tissue Contour Deformity	0	0.0%
Malposition	18	16.1%
Wrinkling/Rippling	0	0.0%
Implant Palpability/Visibility	0	0.0%
Asymmetry	2	1.8%
Ptosis	15	13.4%
Scarring	10	8.9%
Injury - Iatrogenic or Traumatic	0	0.0%
Breast Cancer	1	0.9%
Need for Biopsy	10	8.9%
Patient Request		
Style/Size Change	6	5.4%
Media Anxiety	2	1.8%
Other	0	0.0%
Total	112	100.0%

* Some reoperations were performed for multiple reasons; only the primary reason is provided in the table. In cases where multiple reasons for reoperation were given, the primary reason was determined using a hierarchy as defined by the listed ordering of reasons.

Table 166A: Reasons for Reoperation

Reason	Procedures n	Procedures %(N = 175)
Device Malfunction - Rupture	2	1.1%
Infection	0	0.0%
Capsular Contracture	52	29.7%
Extrusion	1	0.6%
Necrosis	1	0.6%
Healing Related		
Hematoma/Seroma	5	2.9%
Delayed Wound Healing	5	2.9%
Nipple Complications	2	1.1%
Pain	1	0.6%
Unsatisfactory Cosmetic Result		
Breast Tissue Contour Deformity	0	0.0%
Malposition	28	16.0%
Wrinkling/Rippling	0	0.0%
Implant Palpability/Visibility	0	0.0%
Asymmetry	5	2.9%
Ptosis	27	15.4%
Scarring	17	9.7%
Injury - Iatrogenic or Traumatic	0	0.0%
Breast Cancer	1	0.6%
Need for Biopsy	10	5.7%
Patient Request		
Style/Size Change	13	7.4%
Media Anxiety	5	2.9%
Other	0	0.0%
Total	175	100.0%

Table 167: Primary* Procedure Performed

Procedure	Patient Reoperations	
	n	%(N = 112)
Implant Removal		
Without Replacement	5	4.5%
With Replacement**	27	24.1%
Capsule Procedure		
Capsulotomy	15	13.4%
Capsulorraphy	3	2.7%
Capsulectomy	8	7.1%
Wound Repair	2	1.8%
Scar Revision	11	9.8%
Reposition Implant	5	4.5%
Flap Procedure	0	0.0%
Pocket Revision	3	2.7%
Surgical Exploration of Breast Area or Implant	1	0.9%
Aspiration of Hematoma/Seroma	5	4.5%
Mastopexy	15	13.4%
Breast Reduction	0	0.0%
Liposuction	0	0.0%
Removal of Excess Tissue/Lesion/Cyst	0	0.0%
Mastectomy	0	0.0%
Revision of Nipple Reconstruction/Tattoo	1	0.9%
Biopsy	10	8.9%
Other	1	0.9%
Total	112	100.0%

* Some reoperations involved multiple procedures. Only the primary procedure is provided in the table. In cases where multiple procedures were performed, the primary procedure was determined using a hierarchy as defined by the listed ordering of procedures.

** Includes 1 patient who had delayed replacement. This patient had a device removal without replacement in 3/99, and then had a new device placed in 9/99.

Table 167 (cont.): Primary* Procedure Performed

Other Procedure Specified (N = 1)

Reop Seq#	Other Procedure Specified
001	SUTURE REMOVAL
001	SUTURE REMOVAL

CORE STUDY - AUGMENTATION

Table 168: Primary* Reason For Reoperation and Primary Procedure Performed

Reason	Procedure	Patient Reoperations n	Patient Reoperations %(N = 112)
Device Rupture	Implant Replacement/Removal	1	0.9%
Capsular Contracture	Implant Replacement/Removal	16	14.3%
	Capsule Procedure	19	17.0%
Extrusion	Implant Replacement/Removal	1	0.9%
Necrosis	Wound Repair	1	0.9%
Healing Related	Wound Repair	1	0.9%
	Other	1	0.9%
	Revision of Nipple Reconstruction/Tattoo	1	0.9%
	Mastopexy	1	0.9%
	Aspiration of Hematoma/Seroma	5	4.5%
Pain	Capsule Procedure	1	0.9%
Unsatisfactory Cosmetic Result	Implant Replacement/Removal	5	4.5%
	Capsule Procedure	6	5.4%
	Mastopexy	14	12.5%
	Scar Revision	11	9.8%
	Reposition Implant	5	4.5%
	Pocket Revision	3	2.7%
	Surgical Exploration of Breast Area or Implan	1	0.9%
Breast Cancer	Implant Replacement/Removal	1	0.9%
Need for Biopsy	Biopsy	10	8.9%
Patient Request	Implant Replacement/Removal	8	7.1%
Total		112	100.0%

CORE STUDY - AUGMENTATION

Table 168 (cont.): Primary* Reason For Reoperation and Primary Procedure Performed

* Some reoperations involved multiple reasons for reoperation and/or multiple procedures performed. Only the primary reason/procedure is provided in the table. In cases where multiple reasons/procedures were given, the primary reason/procedure was determined using a hierarchy.

Table 169: Number of Procedures Performed Per Reoperation

Number of Procedures	Reoperations	
	n	%(N = 112)
1	41	36.6%
2	43	38.4%
3	3	2.7%
4	18	16.1%
5	2	1.8%
6	5	4.5%
Total	112	100.0%
Total Number of Procedures	248*	

* Total number of procedures is calculated as:
(.41 * 1 procedure) + (43 * 2 procedures) + (3 * 3 procedures)
+ (18 * 4 procedures) + (2 * 5 procedures)
+ (5 * 6 procedures) = 248 procedures.

Table 170: Type of Procedure Performed During Reoperation

Type of Procedure	Procedures n	Procedures %(N = 248)
Implant Removal		
Without Replacement	9	3.6%
With Replacement	51	20.6%
Capsule Procedure		
Capsulotomy	47	19.0%
Capsulorraphy	4	1.6%
Capsulectomy	28	11.3%
Wound Repair	2	0.8%
Scar Revision	21	8.5%
Reposition Implant	14	5.6%
Flap Procedure	0	0.0%
Pocket Revision	5	2.0%
Surgical Exploration of Breast Area or Implant	2	0.8%
Aspiration of Hematoma/Seroma	5	2.0%
Mastopexy	42	16.9%
Breast Reduction	0	0.0%
Liposuction	0	0.0%
Removal of Excess Tissue/Lesion/Cyst	1	0.4%
Mastectomy	1	0.4%
Revision of Nipple Reconstruction/Tattoo	3	1.2%
Biopsy	11	4.4%
Other	2	0.8%
Total	248	100.0%

Table 170 (cont.): Primary* Procedure Performed

Other Procedure Specified (N = 2)

Procedure Seq#	Other Procedure Specified
001	SUTURE REMOVAL
002	SUTURE REMOVAL

CORE STUDY - AUGMENTATION

Table 171: Risk of First Occurrence of Implant Replacement/Removal

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	482	0.0% --	0	963	0.0% --
6 Months	4	477	0.8% (0.0%, 1.6%)	7	954	0.7% (0.2%, 1.3%)
1 Year	13	464	2.7% (1.3%, 4.2%)	24	929	2.5% (1.5%, 3.5%)
2 Years	22	432	4.7% (2.8%, 6.6%)	41	866	4.3% (3.0%, 5.6%)
3 Years	31	309	7.2% (4.7%, 9.7%)	58	621	6.8% (5.0%, 8.4%)

CORE STUDY - AUGMENTATION

Table 172: Risk of First Occurrence of Implant Removal With Replacement

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	482	0.0% --	0	963	0.0% --
6 Months	4	477	0.8% (0.0%, 1.6%)	7	954	0.7% (0.2%, 1.3%)
1 Year	13	464	2.7% (1.3%, 4.2%)	24	929	2.5% (1.5%, 3.5%)
2 Years	21	432	4.4% (2.6%, 6.3%)	39	866	4.1% (2.9%, 5.4%)
3 Years	27	309	6.1% (3.9%, 8.4%)	51	621	5.8% (4.3%, 7.4%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 173: Risk of First Occurrence of Implant Removal Without Replacement

	By Patient				By Implant			
	Number Affected	Number Remaining		Cumulative Risk	Number Affected	Number Remaining		Cumulative Risk
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	482	0.0%	--	0	963	0.0%	--
6 Months	0	474	0.0%	--	0	948	0.0%	--
1 Year	0	462	0.0%	--	0	925	0.0%	--
2 Years	1	432	0.2%	(0.0%, 0.7%)	2	866	0.2%	(0.0%, 0.5%)
3 Years	4	309	1.1%	(0.0%, 2.3%)	7	621	1.0%	(0.3%, 1.7%)

Attachment 2

CORE STUDY - AUGMENTATION

Table 173A: Distribution of Resolution Status of Primary Reason for Implant Removal/Replacement

Resolution Status	By Patient n	By Patient %(N = 58)
Not Yet Resolved		
Undergoing Treatment	26	44.8%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	26	44.8%
Resolved		
With Reoperation and Explantation*	32	55.2%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	32	55.2%

* Includes biopsy (n=0), size change (n=12), media anxiety (n=0) or unknown (n=0). Reoperations performed for these reasons do not require physicians to fill out a corresponding complication form, which documents the resolution status. Therefore, we assume they are resolved after reoperation, either with or without explantation.

Table 174: Primary* Reason for Implant Replacement/Removal

Reason	Implant Removals	
	n	%(N = 58)
Device Malfunction - Rupture	2	3.5%
Infection	0	0.0%
Capsular Contracture	25	43.1%
Extrusion	1	1.7%
Necrosis	0	0.0%
Healing Related		
Hematoma/Seroma	0	0.0%
Delayed Wound Healing	0	0.0%
Nipple Complications	0	0.0%
Pain	0	0.0%
Unsatisfactory Cosmetic Result		
Breast Tissue Contour Deformity	0	0.0%
Malposition	6	10.3%
Wrinkling	0	0.0%
Implant Palpability/Visibility	0	0.0%
Asymmetry	3	5.2%
Ptosis	2	3.5%
Scarring	0	0.0%
Injury - Iatrogenic or Traumatic	0	0.0%
Breast Cancer	1	1.7%
Need for Biopsy	0	0.0%
Patient Request		
Style/Size Change	13	22.4%
Media Anxiety	5	8.6%
Other	0	0.0%
Total	58	100.0%

* Some implant replacements/removals were performed for multiple reasons. Only the primary reason is provided in the table. In cases where multiple reasons were given, the primary reason was determined using a hierarchy as defined by the listed ordering of reasons.

CORE STUDY - AUGMENTATION

Table 175: Physician Evaluation of Explanted Devices

	Ruptured Implants (n = 2)		Intact (Non-Ruptured) Implants (n = 56)	
Characteristic	Yes(%)	No(%)	Yes(%)	No(%)
Capsule Torn*	0 (0.0%)	2 (100.0%)	0 (0.0%)	56(100.0%)
Extracapsular Gel	0 (0.0%)	2 (100.0%)	0 (0.0%)	56(100.0%)
Gel on Implant Surface	2 (100.0%)	0 (0.0%)	0 (0.0%)	56(100.0%)
Removal Difficult	0 (0.0%)	2 (100.0%)	2 (3.6%)	54(96.4%)

* Capsule not intact

Table 176: Distribution of Type of Replacement Implant

Type of Replacement Implant	By Implant	
	n	%(N = 51)
McGhan Study Device	39	76.5%
McGhan Non-Study Device	4	7.8%
Non-McGhan Medical Device	6	11.8%
Unknown Device Type*	2	3.9%
Total	51	100.0%

* The implanting study physician did not perform the implant replacement/removal procedure for these patients. No information regarding type of replacement implant was able to be obtained from the non-study surgeons who performed these implant replacement/removal procedures.

Table 177: McGhan Replacement Implant Size vs. Primary Implant

Size Change	By Implant	
	n	%(N = 39)
Increase in Size	27	69.2%
No Change in Size	6	15.4%
Decrease in Size	6	15.4%
Total	39	100.0%

CORE STUDY - AUGMENTATION

Table 178: Risk of First Occurrence of Any General Breast Surgery Complication

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	147	339	30.0% (25.9%,34.0%)	270	701	27.5% (24.7%,30.3%)
6 Months	167	317	34.1% (29.9%,38.3%)	300	667	30.6% (27.7%,33.5%)
1 Year	184	292	37.7% (33.4%,42.0%)	328	620	33.6% (30.6%,36.5%)
2 Years	200	260	41.2% (36.8%,45.6%)	356	560	36.7% (33.6%,39.7%)
3 Years	207	188	43.1% (38.6%,47.6%)	369	404	38.5% (35.3%,41.6%)

CORE STUDY - AUGMENTATION

Table 179: Risk of First Occurrence of Any Breast Implant Surgery - Cosmetic Complication

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	9	473	1.9% (0.7%, 3.0%)	11	952	1.1% (0.5%, 1.8%)
6 Months	18	458	3.7% (2.0%, 5.4%)	25	925	2.6% (1.6%, 3.6%)
1 Year	22	444	4.6% (2.7%, 6.4%)	31	899	3.2% (2.1%, 4.4%)
2 Years	32	411	6.8% (4.5%, 9.0%)	46	833	4.9% (3.5%, 6.3%)
3 Years	38	297	8.5% (5.9%,11.1%)	56	598	6.4% (4.7%, 8.0%)

CORE STUDY - AUGMENTATION

Table 180: Risk of First Occurrence of Any Breast Implant Surgery - NonCosmetic Complication

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	480	0.4% (0.0%, 1.0%)	2	961	0.2% (0.0%, 0.5%)
6 Months	22	459	4.6% (2.7%, 6.4%)	32	929	3.3% (2.2%, 4.5%)
1 Year	41	436	8.5% (6.0%,11.0%)	67	886	7.0% (5.4%, 8.6%)
2 Years	52	405	10.9% (8.1%,13.7%)	84	826	8.8% (7.0%,10.6%)
3 Years	58	289	12.6% (9.5%,15.7%)	95	590	10.4% (8.4%,12.4%)

Table 181: Pre-Implant Reproduction Problems

Reproduction Problems	Patients n	Patients %(N = 494)
No Reproduction Problem	413	83.6%
Reproduction Problem	81	16.4%
	494	100.0%

Type Of Reproduction Problems	n	%(N = 81)
Infertility	20	24.7%
Spontaneous Abortion (Miscarriage)	51	63.0%
Planned Abortion to Treat a Medical Problem	9	11.1%
Ectopic Pregnancy	9	11.1%
Stillbirth	0	0.0%
Other	5	6.2%
	94*	116.0%

* The sum of reproduction problems listed may exceed the total number of patients with reproduction problems because a patient may have had more than one reproduction problem.

Table 181 (cont.): Pre-Implant Reproduction Problems

Other Reproduction Problem Specified (N = 5)

Pt Seq#	Other Reproduction Problem Specified
001	CERVICAL LIGATION PLACENTIA PREVIA
002	HSYTERECTOMY DONE FOR UNKNOWN REASONS
003	HYSTERECTOMY DONE FOR UNKNOWN REASONS
004	ENDOMETRIOSIS
005	HYSTERECTOMY DONE FOR UNKNOWN REASONS

Table 182: Post-Implant Reproduction Problems Through 3 Years

Reproduction Problems	Patients n	Patients %(N = 494)
No Reproduction Problem	486	98.4%
Reproduction Problem	8	1.6%
	494	100.0%

Type Of Reproduction Problems	n	%(N = 8)
Infertility	0	0.0%
Spontaneous Abortion (Miscarriage)	7	87.5%
Planned Abortion to Treat a Medical Problem	0	0.0%
Ectopic Pregnancy	1	12.5%
Stillbirth	0	0.0%
Other	1	12.5%
	9*	112.5%

* The sum of reproduction problems listed may exceed the total number of patients with reproduction problems because a patient may have had more than one reproduction problem.

CORE STUDY - AUGMENTATION

Table 182 (cont.): Post-Implant Reproduction Problems Through 3 Years

Other Reproduction Problem Specified (N = 1)

Pt Seq#	Other Reproduction Problem Specified
001	ENDOMETRIOSIS

CORE STUDY - AUGMENTATION

Table 183: Pre-Implantation Lactation Problems

	Patients	
Lactation Problems	n	%(N = 494)
No Lactation Problem	452	91.5%
Lactation Problem	42	8.5%
	494*	100.0%

Type Of Lactation Problem	n	%(N = 42)
Mastitis Not Requiring Treatment	6	14.3%
Mastitis Requiring Treatment	16	38.1%
Inadequate Milk Production	19	45.2%
Excess Milk Production	4	9.5%
Pain	5	11.9%
Other	2	4.8%
	52**	123.8%

* 276 patients attempted to breastfeed.
** The sum of lactation problems listed may exceed the total number of patients with lactation problems because a patient may have had more than one lactation problem.

Table 183 (cont.): Pre-Implant Lactation Problems

Other Lactation Problem Specified (N = 2)

Pt Seq#	Other Lactation Problem Specified
001	CHOLIC
002	CLOGGED MILK DUCT

Table 184: Post-Implant Lactation Problems Through 3 Years

Lactation Problems	Patients n	Patients %(N = 494)
No Lactation Problem	489	99.0%
Lactation Problem	5	1.0%
	494*	100.0%

Type Of Lactation Problem	n	%(N = 5)
Mastitis Not Requiring Treatment	1	20.0%
Mastitis Requiring Treatment	2	40.0%
Inadequate Milk Production	4	80.0%
Excess Milk Production	1	20.0%
Pain	1	20.0%
Other	1	20.0%
	10**	200.0%

* 32 patients attempted to breastfeed.

** The sum of lactation problems listed may exceed the total number of patients with lactation problems because a patient may have had more than one lactation problem.

Table 184 (cont.): Post-Implant Lactation Problems Through 3 Years

Other Lactation Problem Specified (N = 1)

Pt Seq#	Other Lactation Problem Specified
001	DECREASE VOLUME MILK (STILL ADEQUATE)

Table 185: Pre-Implant Breast Disease

	Patients	
Breast Disease	n	%(N = 494)
No Breast Disease	464	93.9%
Breast Disease	30	6.1%
	494	100.0%

Type Of Breast Disease	n	%(N = 30)
Benign Disease	29	96.7%
Unknown Breast Disease*	1	3.3%
	30	100.0%

* This patient's pre-operative mammogram indicated a cyst, most likely benign. The patient's physician recommended a follow-up mammogram in 6 months to confirm the benign finding; this patient did not obtain a follow-up mammogram.

Table 186: Post-Implant Breast Disease Through 3 Years

	Patients	
Breast Disease	n	%(N = 494)
No Breast Disease	462	93.5%
Breast Disease	32	6.5%
	494	100.0%

Type of Breast Disease	n	%(N = 32)
Confirmed Malignant Disease	1	3.1%
Benign Disease	29	90.6%
Unknown Breast Disease*	2	6.3%
	32	100.0%

* One patient had a breast lump noted during her 1 year follow-up exam and was referred for a mammogram; the patient has not yet had the recommended diagnostic mammogram.

One patient reported a breast lump during her 3-year follow-up exam and was referred to another physician for follow-up; the patient is due to return for her first follow-up appointment since the referral in May or June this year.

Table 187: Pre-Implant Mammogram Result

Mammogram Results	Patients n	Patients %(N = 494)
No Pre-Implant Mammogram	309	62.6%
Pre-Implant Mammogram		
Normal Mammogram	180	36.4%
Abnormal Mammogram	5	1.0%
	494	100.0%

Disposition Of Patients With Abnormal Mammogram Results	n	%(N = 5)
Benign Disease	4	80.0%
Unknown Breast Disease*	1	20.0%
	5	100.0%

* This patient's pre-operative mammogram indicated a cyst, most likely benign. The patient's physician recommended a follow-up mammogram in 6 months to confirm the benign finding; this patient did not obtain a follow-up mammogram.

Table 188: Post-Implant Mammogram Result Through 3 Years

Mammogram Results	Patients n	Patients %(N = 494)
No Post-Implant Mammogram	343	69.4%
Post-Implant Mammogram		
Normal Mammogram	139	28.1%
Abnormal Mammogram	12	2.4%
	494	100.0%

Disposition of Patients With Abnormal Mammogram Results	n	%(N = 12)
No Breast Disease	1	8.3%
Benign Disease	11	91.7%
	12	100.0%

Table 189: Pre-Implant Connective Tissue/Autoimmune Disease (CTD)

CTD	Patients	
	n	%(N = 494)
No CTD	494	100.0%
CTD		
Confirmed CTD	0	0.0%
Unconfirmed CTD	0	0.0%
Total	494	100.0%

CORE STUDY - AUGMENTATION

Table 190: Post-Implant Connective Tissue/Autoimmune Disease (CTD) Through 3 Years

CTD	Patients n	Patients %(N = 494)
No CTD	493	99.8%
CTD		
Confirmed CTD	1	0.2%
Unconfirmed CTD	0	0.0%
Total	494	100.0%

Confirmed CTD Specified (N = 1)

Pt Seq#	CTD Specified	# of Months Between Implant Surgery and Onset
001	Rheumatoid Arthritis	11

Appendix D: List of Complications Occurring Beyond 2 Years (730 Days) Post-Implant

Complication	# of Post 2-Year Occurrences	
	Patients (N = 16)	Implants (N = 24)
Asymmetry	1	1
Breast Pain	2	2
Bruising	0	0
Capsule Calcification	0	0
Capsular Contracture	9	14
Delayed Wound Healing	1	1
Fluid Accumulation	0	0
Hematoma	0	0
Hypertrophic Scarring	1	1
Implant Extrusion	0	0
Implant Malposition	4	5
Implant Palpability	0	0
Implant Visibility	0	0
Infection	0	0
Irritation	0	0
Loss of Nipple Sensation	0	0
Loss of Skin Sensation	0	0
Lymphadenopathy	0	0
Lymphedema	0	0
Nipple Hypersensitivity	0	0
Nipple Paresthesia	0	0
Other Abnormal Scarring	0	0
Other Nipple Related Observation	0	0

Appendix D (cont.): List of Complications Occurring Beyond 2 Years (730 Days) Post-Implant

Complication	# of Post 2-Year Occurrences	
	Patients (N = 16)	Implants (N = 24)
Pneumothorax	0	0
Ptosis	2	3
Redness	1	1
Seroma	0	0
Skin Hypersensitivity	0	0
Skin Paresthesia	0	0
Skin Rash	0	0
Swelling	0	0
Tissue or Skin Necrosis	0	0
Wrinkling/Rippling	1	1
Other Complications	1	2

Appendix G: 3-Year Complication Rates for Augmentation Patients in Core Study and 1995 Saline Study

Complication	Core 3-Year Risk By Patient	A95 3-Year Risk By Patient
Swelling	23.3% (19.5%, 27.0%)	N/A
Reoperation	20.6% (16.8%, 24.4%)	21.1% (18.4%, 23.8%)
Bruising	9.3% (6.7%, 11.9%)	N/A
Capsular Contracture	8.3% (5.8%, 10.9%)	8.7% (6.8%, 10.6%)
Hypertrophic/Abnormal Scarring	8.1% (5.7%, 10.6%)	6.4% (4.8%, 8.0%)
Implant Replacement/Removal	7.2% (4.7%, 9.7%)	7.6% (5.8%, 9.4%)
Breast Pain	6.2% (4.0%, 8.4%)	15.6% (13.2%, 17.9%)
Ptosis	3.3% (1.7%, 5.0%)	N/A
Skin Rash	3.1% (1.6%, 4.6%)	1.6% (0.8%, 2.4%)
Implant Malposition	3.1% (1.5%, 4.8%)	8.2% (6.3%, 10.0%)
Loss of Nipple Sensation	3.1% (1.6%, 4.7%)	8.4% (6.5%, 10.2%)
Asymmetry	2.8% (1.3%, 4.4%)	10.1% (8.1%, 12.1%)
Other Nipple Related Observation	2.8% (1.3%, 4.2%)	N/A
Seroma/Fluid Accumulation	2.7% (1.3%, 4.1%)	2.6% (1.6%, 3.7%)
Redness	2.6% (1.1%, 4.1%)	N/A
Implant Rupture/Deflation	1.2% (0.1%, 2.2%)	5.0% (3.5%, 6.4%)
Loss of Skin Sensation	1.2% (0.3%, 2.2%)	N/A
Delayed Wound Healing	1.1% (0.1%, 2.1%)	0.7% (0.1%, 1.2%)
Infection	1.0% (0.1%, 1.9%)	0.7% (0.1%, 1.2%)
Hematoma	1.0% (0.1%, 1.9%)	1.6% (0.7%, 2.4%)
Wrinkling/Rippling	0.7% (0.0%, 1.6%)	10.5% (8.4%, 12.6%)
Implant Palpability/Visibility	0.6% (0.0%, 1.3%)	9.2% (7.2%, 11.1%)
Lymphadenopathy	0.4% (0.0%, 1.0%)	0.5% (0.0%, 1.0%)
Nipple Hypersensitivity	0.4% (0.0%, 1.0%)	N/A
Nipple Paresthesia	0.4% (0.0%, 1.0%)	9.3% (7.4%, 11.2%)
Skin Paresthesia	0.4% (0.0%, 1.0%)	7.2% (5.5%, 9.0%)
Other Complications	0.2% (0.0%, 0.6%)	2.3% (1.3%, 3.3%)
Implant Extrusion	0.2% (0.0%, 0.6%)	0.1% (0.0%, 0.4%)
Capsule Calcification	0.2% (0.0%, 0.7%)	1.2% (0.4%, 1.9%)
Tissue or Skin Necrosis	0.2% (0.0%, 0.6%)	0.7% (0.1%, 1.2%)
Lymphedema	0.2% (0.0%, 0.6%)	N/A
Irritation	0.0% --	2.9% (1.8%, 4.0%)
Pneumothorax	0.0% --	0.1% (0.0%, 0.3%)
Skin Hypersensitivity	0.0% --	N/A

Appendix H1: Summary of Complications Following Primary Implant Removal With Replacement

Complication	# of Occurrences	
	Patients (N = 4)	Implants (N = 5)
Asymmetry*	1	2
Breast Pain*	2	3
Breast Ptosis**	0	0
Bruising**	0	0
Capsular Contracture*	1	2
Capsule Calcification*	1	2
Delayed Wound Healing*	0	0
Fluid Accumulation**	0	0
Hematoma**	0	0
Hypertrophic Scarring**	0	0
Implant Extrusion**	1	1
Implant Malposition*	0	0
Implant Palpability*	0	0
Implant Visibility*	0	0
Infection**	0	0
Irritation*	0	0
Loss of Nipple Sensation*	0	0
Loss of Skin Sensation*	0	0
Lymphadenopathy**	1	1
Lymphedema**	0	0
Nipple Hypersensitivity*	0	0
Nipple Paresthesia*	0	0
Other Abnormal Scarring**	1	1
Other Nipple Related Observation**	0	0

Appendix H1 (cont.): Summary of Complications Following Primary Implant Removal With Replacement

Complication	# of Occurrences	
	Patients (N = 4)	Implants (N = 5)
Pneumothorax**	0	0
Redness**	0	0
Seroma**	0	0
Skin Hypersensitivity*	0	0
Skin Paresthesia*	0	0
Skin Rash**	0	0
Swelling**	1	1
Tissue/Skin Necrosis**	0	0
Wrinkling/Rippling*	0	0
Other Complications**	0	0
Seroma/Fluid Accumulation**	0	0
Implant Palpability/Visibility*	0	0
Hypertrophic/Other Abnormal Scarring**	1	1
Nipple Hypersensitivity/Paresthesia/ Loss of Nipple Sensation*	0	0
Skin Hypersensitivity/Paresthesia/ Loss of Skin Sensation*	0	0

* >= Moderate Severity
** All Severity Levels

Appendix H1 (cont.): Summary of Complications Following Primary Implant Removal With Replacement

Detailed Listing of Occurrence/Report of All Complications Following Implant Replacement Among Augmentation Patients

PT	SIDE	complication	Surgery date	Onset date	Resolution date
	L	Asymmetry	08/12/1999	08/20/2002	12/17/2002
	R	Asymmetry	08/12/1999	08/20/2002	12/17/2002
	R	Breast Pain	11/18/1999	11/02/2001	11/20/2001
	L	Breast Pain	08/12/1999	09/18/2000	09/26/2000
	R	Breast Pain	08/12/1999	09/18/2000	09/26/2000
	L	Capsular Contracture	08/12/1999	08/20/2002	12/17/2002
	R	Capsular Contracture	08/12/1999	08/20/2002	12/17/2002
	L	Capsule Calcification	08/12/1999	08/24/2000	
	R	Capsule Calcification	08/12/1999	08/24/2000	
	L	Implant Extrusion	02/11/1999	09/01/1999	10/18/1999
	L	Lymphadenopathy	05/01/1999	08/30/2000	
	L	Other Abnormal Scarring	02/11/1999	06/15/1999	06/28/1999
	L	Swelling	08/12/1999	01/25/2000	02/04/2000
	L	Hypertrophic : Other Abnormal Scarring	02/11/1999	06/15/1999	06/28/1999