Adjunct Clinical Study
Revision Cohort
Risks of First Occurrence

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Table 8: 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)
1 Year	73	2777	2.1% (1.6%, 2.6%)	90	5352	1.3% (1.1%, 1.6%)
3 Years	163	346	9.8% (7.9%,11.6%)	200	663	6.4% (5.3%, 7.5%)

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Table 9: 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)
1 Year	92	2774	2.5% (2.0%, 3.0%)	127	5338	1.8% (1.5%, 2.1%)
3 Years	150	346	7.8% (6.1%, 9.4%)	203	660	5.6% (4.5%, 6.6%)

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Table 10A: 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)
1 Year	97	2763	2.5% (2.0%, 3.0%)	177	5307	2.4% (2.0%, 2.7%)
3 Years	108	342	3.2% (2.6%, 3.8%)	194	651	2.9% (2.5%, 3.4%)

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Table 10B: 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)
1 Year	20	2788	0.5% (0.3%, 0.8%)	29	5353	0.4% (0.3%, 0.5%)
3 Years	23	349	0.7% (0.4%, 1.1%)	32	665	0.5% (0.3%, 0.7%)

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Table 11: Risk of First Occurrence of Capsular Contracture

	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)
1 Year	164	2765	4.7% (4.0%, 5.4%)	223	5335	3.3% (2.9%, 3.8%)
3 Years	365	332	20.0% (17.6%,22.3%)	505	642	15.2% (13.6%,16.8%)

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Table 12: 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)
1 Year	20	2797	0.6% (0.3%, 0.9%)	29	5366	0.5% (0.3%, 0.6%)
3 Years	53	351	3.4% (2.3%, 4.5%)	76	668	2.4% (1.7%, 3.1%)

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Table 13: 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)
1 Year	10	2793	0.3% (0.1%, 0.4%)	12	5363	0.2% (0.1%, 0.3%)
3 Years	15	351	0.6% (0.2%, 1.1%)	17	668	0.4% (0.1%, 0.6%)

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Table 14A: 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)
1 Year	16	2789	0.4% (0.2%, 0.6%)	17	5360	0.2% (0.1%, 0.3%)
3 Years	25	347	0.9% (0.5%, 1.3%)	32	660	0.7% (0.4%, 0.9%)

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Table 14B: 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)
1 Year	9	2793	0.2% (0.1%, 0.4%)	9	5363	0.1% (0.0%, 0.2%)
3 Years	13	351	0.5% (0.2%, 0.8%)	13	668	0.2% (0.1%, 0.4%)

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Table 15A: Risk of First Occurrence of Hypertrophic 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)
1 Year	30	2791	0.9% (0.6%, 1.2%)	50	5358	0.8% (0.6%, 1.0%)
3 Years	87	339	4.4% (3.4%, 5.4%)	141	648	3.6% (3.0%, 4.3%)

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Table 15B: Risk of First Occurrence of Hypertrophic 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)
1 Year	10	2795	0.3% (0.1%, 0.5%)	16	5363	0.3% (0.1%, 0.4%)
3 Years	40	346	2.0% (1.3%, 2.7%)	61	660	1.5% (1.1%, 2.0%)

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Table 16: 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)
1 Year	9	2795	0.2% (0.1%, 0.4%)	12	5365	0.2% (0.1%, 0.3%)
3 Years	16	346	0.6% (0.3%, 1.0%)	26	658	0.6% (0.3%, 0.8%)

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Table 17: 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)
1 Year	61	2785	1.8% (1.3%, 2.2%)	75	5358	1.1% (0.9%, 1.4%)
3 Years	126	345	7.3% (5.6%, 8.9%)	158	662	4.8% (3.8%, 5.8%)

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Table 18: Risk of First Occurrence of Implant Palpability

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

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Table 19: Risk of First Occurrence of Implant Rupture (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)
1 Year	12	2794	0.3% (0.1%, 0.5%)	14	5365	0.2% (0.1%, 0.3%)
3 Years	30	346	2.7% (1.4%, 3.9%)	39	659	1.8% (1.0%, 2.5%)

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Table 20: 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)
1 Year	77	2781	2.3% (1.8%, 2.8%)	104	5351	1.6% (1.3%, 1.9%)
3 Years	213	333	13.6% (11.4%,15.8%)	307	644	10.4% (9.0%,11.8%)

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Table 21A: 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)
1 Year	24	2791	0.6% (0.4%, 0.9%)	31	5360	0.4% (0.3%, 0.6%)
3 Years	35	346	1.4% (0.9%, 2.0%)	48	659	1.0% (0.7%, 1.4%)

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Table 21B: 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)
1 Year	16	2793	0.4% (0.2%, 0.6%)	20	5363	0.3% (0.2%, 0.4%)
3 Years	19	351	0.7% (0.3%, 1.2%)	23	668	0.4% (0.2%, 0.7%)

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Table 22: 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)
1 Year	5	2795	0.1% (0.0%, 0.2%)	5	5365	0.1% (0.0%, 0.1%)
3 Years	9	350	0.4% (0.1%, 0.8%)	10	667	0.3% (0.1%, 0.5%)

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Table 23: Risk of First Occurrence of Loss of Nipple Sensation

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

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Table 24A: 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)
1 Year	7	2795	0.2% (0.0%, 0.3%)	9	5365	0.1% (0.0%, 0.2%)
3 Years	24	344	1.5% (0.8%, 2.2%)	39	656	1.2% (0.8%, 1.7%)

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Table 24B: 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)
1 Year	3	2796	0.1% (0.0%, 0.2%)	3	5365	0.0% (0.0%, 0.1%)
3 Years	5	350	0.3% (0.0%, 0.6%)	5	667	0.1% (0.0%, 0.3%)

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Table 25: Risk of First Occurrence of Nipple Hypersensitivity

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

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Table 26: Risk of First Occurrence of Nipple Paresthesia/Hypersensitivity/ 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)
1 Year	33	2545	1.1% (0.7%, 1.4%)	51	4885	0.9% (0.6%, 1.1%)
3 Years	89	341	5.5% (4.1%, 6.9%)	139	652	4.5% (3.6%, 5.5%)

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Table 27: 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)
1 Year	5	2795	0.1% (0.0%, 0.3%)	6	5365	0.1% (0.0%, 0.2%)
3 Years	11	347	0.5% (0.2%, 0.8%)	18	660	0.4% (0.2%, 0.7%)

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Table 28A: 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)
1 Year	44	2781	1.2% (0.8%, 1.5%)	62	5347	0.9% (0.6%, 1.1%)
3 Years	60	343	2.6% (1.7%, 3.4%)	85	654	1.9% (1.3%, 2.4%)

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Table 28B: 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)
1 Year	22	2789	0.6% (0.3%, 0.8%)	28	5359	0.4% (0.2%, 0.5%)
3 Years	28	350	1.0% (0.6%, 1.5%)	34	667	0.6% (0.4%, 0.9%)

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Table 29A: Risk of First Occurrence of Seroma (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)
1 Year	20	2790	0.5% (0.3%, 0.8%)	22	5360	0.3% (0.2%, 0.4%)
3 Years	30	346	1.5% (0.7%, 2.2%)	38	659	1.0% (0.6%, 1.4%)

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Table 29B: Risk of First Occurrence of Seroma(>= 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)
1 Year	12	2794	0.3% (0.1%, 0.5%)	13	5364	0.2% (0.1%, 0.3%)
3 Years	13	350	0.5% (0.1%, 0.9%)	14	667	0.3% (0.1%, 0.5%)

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Table 30: Risk of First Occurrence of Skin Hypersensitivity

N/A: SKIN HYPERSENSITIVITY AS BEEN COMBINED WITH SKIN PARESTHESIA

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Table 31: Risk of First Occurrence of Skin Paresthesia/Hypersensitivity(>= 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)
1 Year	14	2795	0.4% (0.2%, 0.6%)	18	5365	0.3% (0.1%, 0.4%)
3 Years	35	349	2.0% (1.2%, 2.8%)	45	666	1.3% (0.8%, 1.8%)

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Table 32A: 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)
1 Year	15	2791	0.4% (0.2%, 0.6%)	26	5357	0.4% (0.2%, 0.5%)
3 Years	32	346	1.9% (1.0%, 2.8%)	54	658	1.5% (1.0%, 2.0%)

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Table 32B: 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)
1 Year	6	2795	0.2% (0.0%, 0.3%)	11	5363	0.2% (0.1%, 0.3%)
3 Years	8	350	0.6% (0.0%, 1.3%)	13	666	0.4% (0.1%, 0.7%)

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Table 33A: 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)
1 Year	170	2738	4.4% (3.8%, 5.1%)	302	5267	4.1% (3.6%, 4.5%)
3 Years	191	338	6.1% (5.0%, 7.2%)	332	646	5.2% (4.6%, 5.9%)

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Table 33B: 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)
1 Year	58	2775	1.5% (1.1%, 1.9%)	86	5337	1.2% (0.9%, 1.4%)
3 Years	63	347	1.9% (1.4%, 2.5%)	92	662	1.4% (1.1%, 1.7%)

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Table 34A: Risk of First Occurrence of Tissue or 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)
1 Year	7	2795	0.2% (0.0%, 0.3%)	10	5365	0.1% (0.1%, 0.2%)
3 Years	17	345	0.9% (0.4%, 1.5%)	29	657	0.9% (0.5%, 1.3%)

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Table 34B: Risk of First Occurrence of Tissue or 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)
1 Year	1	2797	0.0% (0.0%, 0.1%)	2	5366	0.0% (0.0%, 0.1%)
3 Years	2	351	0.2% (0.0%, 0.6%)	4	668	0.2% (0.0%, 0.5%)

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Table 35: Risk of First Occurrence of Wrinkling(>= 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)
1 Year	77	2788	2.3% (1.8%, 2.8%)	108	5355	1.7% (1.3%, 2.0%)
3 Years	185	339	10.6% (8.7%,12.5%)	273	651	8.3% (7.1%, 9.6%)

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Table 36A: 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)
1 Year	32	2792	0.9% (0.6%, 1.2%)	42	5360	0.6% (0.4%, 0.8%)
3 Years	54	347	2.3% (1.6%, 3.1%)	71	662	1.6% (1.2%, 2.1%)

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Table 36B: 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)
1 Year	13	2797	0.4% (0.2%, 0.6%)	18	5366	0.3% (0.1%, 0.4%)
3 Years	22	351	1.0% (0.5%, 1.5%)	28	668	0.6% (0.4%, 0.9%)