A95/R95 Clinical Study

Analysis of Revision Patients in Augmentation and Reconstruction Cohorts

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Table 1: Revision: Risk of First Occurrence of Asymmetry

	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	110	0.0% (0.0%, 0.0%)		N/A	
6 Months	3	102	2.8% (0.0%, 5.9%)		N/A	
1 Year	8	90	7.8% (2.6%, 13.0%)		N/A	
2 Years	12	63	12.5% (5.8%, 19.1%)		N/A	
3 Years	16	44	18.6% (10.1%, 27.2%)		N/A	

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Table 2: Revision: Risk of First Occurrence of Breast Pain

	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	102	7.2% (2.4%, 12.1%)	11	146	7.0% (3.0%, 10.9%)
6 Months	11	96	10.0% (4.4%, 15.7%)	14	134	9.0% (4.5%, 13.5%)
1 Year	12	89	11.0% (5.1%, 16.9%)	15	122	9.7% (5.0%, 14.4%)
2 Years	16	62	15.4% (8.4%, 22.4%)	19	87	12.9% (7.4%, 18.4%)
3 Years	18	44	18.4% (10.5%, 26.3%)	21	62	15.1% (9.0%, 21.3%)

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Table 3: Revision: 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)
4 Weeks	2	108	1.8% (0.0%, 4.3%)	3	154	1.9% (0.0%, 4.0%)
6 Months	6	100	5.6% (1.2%, 9.9%)	8	140	5.2% (1.7%, 8.7%)
1 Year	8	91	7.5% (2.5%, 12.6%)	10	125	6.7% (2.7%, 10.6%)
2 Years	15	64	15.0% (7.9%, 22.0%)	18	88	12.9% (7.3%, 18.5%)
3 Years	17	45	17.9% (10.0%, 25.7%)	20	63	15.1% (8.9%, 21.3%)

* Capsular contracture is defined as a physician evaluation of a capsule as a III or IV on the Baker Grade Classification scale. If a Baker Grade was not given but 1) capsular contracture was reported specifically, or 2) a capsule treatment was performed and firmness was reported, Baker Grade was assumed to be a IV.

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Table 4: Revision: Risk of First Occurrence of Capsule Calcification

	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	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	1	104	0.9% (0.0%, 2.8%)	1	145	0.7% (0.0%, 2.0%)
1 Year	1	97	0.9% (0.0%, 2.8%)	1	132	0.7% (0.0%, 2.0%)
2 Years	2	70	2.0% (0.0%, 4.8%)	2	96	1.5% (0.0%, 3.5%)
3 Years	4	50	5.7% (0.0%, 11.3%)	5	69	5.4% (0.6%, 10.2%)

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Table 5: Revision: Risk of First Occurrence of Delayed Wound Healing

	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	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	1	105	0.9% (0.0%, 2.7%)	1	146	0.6% (0.0%, 1.9%)
1 Year	1	98	0.9% (0.0%, 2.7%)	1	133	0.6% (0.0%, 1.9%)
2 Years	1	70	0.9% (0.0%, 2.7%)	1	96	0.6% (0.0%, 1.9%)
3 Years	1	51	0.9% (0.0%, 2.7%)	1	70	0.6% (0.0%, 1.9%)

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Table 6: Revision: Risk of First Occurrence of Hematoma

	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	106	3.6% (0.1%, 7.1%)	4	153	2.5% (0.1%, 5.0%)
6 Months	4	101	3.6% (0.1%, 7.1%)	4	142	2.5% (0.1%, 5.0%)
1 Year	4	95	3.6% (0.1%, 7.1%)	4	130	2.5% (0.1%, 5.0%)
2 Years	4	67	3.6% (0.1%, 7.1%)	4	93	2.5% (0.1%, 5.0%)
3 Years	4	50	3.6% (0.1%, 7.1%)	4	69	2.5% (0.1%, 5.0%)

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Table 7: Revision: Risk of First Occurrence of Implant Deflation

	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	106	4.5% (0.6%, 8.3%)	5	153	3.1% (0.4%, 5.8%)
6 Months	8	98	7.2% (2.4%, 12.0%)	9	138	5.7% (2.1%, 9.3%)
1 Year	8	91	7.2% (2.4%, 12.0%)	9	125	5.7% (2.1%, 9.3%)
2 Years	8	65	7.2% (2.4%, 12.0%)	9	90	5.7% (2.1%, 9.3%)
3 Years	11	46	12.1% (5.0%, 19.2%)	12	64	9.3% (4.0%, 14.6%)

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Table 8: Revision: Risk of First Occurrence of Implant Extrusion

	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	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	0	105	0.0% (0.0%, 0.0%)	0	146	0.0% (0.0%, 0.0%)
1 Year	0	98	0.0% (0.0%, 0.0%)	0	133	0.0% (0.0%, 0.0%)
2 Years	0	70	0.0% (0.0%, 0.0%)	0	96	0.0% (0.0%, 0.0%)
3 Years	0	51	0.0% (0.0%, 0.0%)	0	70	0.0% (0.0%, 0.0%)

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Table 9: Revision: Risk of First Occurrence of Implant Malposition

	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	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	1	105	0.9% (0.0%, 2.8%)	1	146	0.7% (0.0%, 2.0%)
1 Year	5	95	4.9% (0.7%, 9.1%)	5	130	3.6% (0.5%, 6.6%)
2 Years	8	68	8.4% (2.8%, 14.0%)	8	94	6.2% (2.0%, 10.3%)
3 Years	11	48	13.1% (5.6%, 20.5%)	12	67	10.9% (4.9%, 16.9%)

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Table 10: Revision: Risk of First Occurrence of Implant Palpability/Visibility

	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	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	5	101	4.7% (0.7%, 8.7%)	5	142	3.3% (0.5%, 6.2%)
1 Year	7	93	6.7% (1.9%, 11.4%)	8	127	5.5% (1.8%, 9.2%)
2 Years	10	64	9.8% (4.0%, 15.6%)	11	89	7.8% (3.4%, 12.3%)
3 Years	16	42	19.5% (10.5%, 28.5%)	18	60	16.0% (8.9%, 23.1%)

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Table 11: Revision: Risk of First Occurrence of Infection

	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	108	1.8% (0.0%, 4.3%)	3	154	1.9% (0.0%, 4.0%)
6 Months	2	103	1.8% (0.0%, 4.3%)	3	143	1.9% (0.0%, 4.0%)
1 Year	3	95	2.8% (0.0%, 6.0%)	4	129	2.6% (0.1%, 5.2%)
2 Years	3	69	2.8% (0.0%, 6.0%)	4	95	2.6% (0.1%, 5.2%)
3 Years	3	51	2.8% (0.0%, 6.0%)	4	70	2.6% (0.1%, 5.2%)

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Table 12: Revision: Risk of First Occurrence of Irritation/Inflammation

	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	109	0.9% (0.0%, 2.7%)	1	156	0.6% (0.0%, 1.9%)
6 Months	1	104	0.9% (0.0%, 2.7%)	1	145	0.6% (0.0%, 1.9%)
1 Year	2	96	1.9% (0.0%, 4.6%)	2	131	1.4% (0.0%, 3.3%)
2 Years	2	69	1.9% (0.0%, 4.6%)	2	95	1.4% (0.0%, 3.3%)
3 Years	2	51	1.9% (0.0%, 4.6%)	2	70	1.4% (0.0%, 3.3%)

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Table 13: Revision: Risk of First Occurrence of Loss of Nipple 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	0	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	1	104	0.9% (0.0%, 2.8%)	2	144	1.4% (0.0%, 3.2%)
1 Year	1	98	0.9% (0.0%, 2.8%)	2	133	1.4% (0.0%, 3.2%)
2 Years	1	70	0.9% (0.0%, 2.8%)	2	96	1.4% (0.0%, 3.2%)
3 Years	1	51	0.9% (0.0%, 2.8%)	2	70	1.4% (0.0%, 3.2%)

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Table 14: Revision: Risk of First Occurrence of Lymphadenopathy

	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	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	0	105	0.0% (0.0%, 0.0%)	0	146	0.0% (0.0%, 0.0%)
1 Year	0	98	0.0% (0.0%, 0.0%)	0	133	0.0% (0.0%, 0.0%)
2 Years	0	70	0.0% (0.0%, 0.0%)	0	96	0.0% (0.0%, 0.0%)
3 Years	0	51	0.0% (0.0%, 0.0%)	0	70	0.0% (0.0%, 0.0%)

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Table 15: Revision: Risk of First Occurrence of Nipple Paresthesia

	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	109	0.9% (0.0%, 2.6%)	1	156	0.6% (0.0%, 1.8%)
6 Months	2	104	1.8% (0.0%, 4.3%)	2	145	1.3% (0.0%, 3.0%)
1 Year	3	97	2.8% (0.0%, 6.0%)	3	132	2.0% (0.0%, 4.3%)
2 Years	4	69	4.1% (0.1%, 8.0%)	5	95	3.8% (0.5%, 7.2%)
3 Years	4	51	4.1% (0.1%, 8.0%)	5	70	3.8% (0.5%, 7.2%)

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Table 16: Revision: Risk of First Occurrence of Pneumothorax

	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	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	0	105	0.0% (0.0%, 0.0%)	0	146	0.0% (0.0%, 0.0%)
1 Year	0	98	0.0% (0.0%, 0.0%)	0	133	0.0% (0.0%, 0.0%)
2 Years	0	70	0.0% (0.0%, 0.0%)	0	96	0.0% (0.0%, 0.0%)
3 Years	0	51	0.0% (0.0%, 0.0%)	0	70	0.0% (0.0%, 0.0%)

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Table 17: Revision: Risk of First Occurrence of Scarring Complications

	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	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	0	105	0.0% (0.0%, 0.0%)	0	146	0.0% (0.0%, 0.0%)
1 Year	2	96	2.0% (0.0%, 4.8%)	2	131	1.5% (0.0%, 3.5%)
2 Years	2	69	2.0% (0.0%, 4.8%)	2	95	1.5% (0.0%, 3.5%)
3 Years	2	51	2.0% (0.0%, 4.8%)	2	70	1.5% (0.0%, 3.5%)

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Table 18: Revision: Risk of First Occurrence of Seroma

	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	108	1.8% (0.0%, 4.3%)	2	155	1.2% (0.0%, 3.0%)
6 Months	2	104	1.8% (0.0%, 4.3%)	2	145	1.2% (0.0%, 3.0%)
1 Year	2	97	1.8% (0.0%, 4.3%)	2	132	1.2% (0.0%, 3.0%)
2 Years	2	69	1.8% (0.0%, 4.3%)	2	95	1.2% (0.0%, 3.0%)
3 Years	2	50	1.8% (0.0%, 4.3%)	2	69	1.2% (0.0%, 3.0%)

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Table 19: Revision: Risk of First Occurrence of Skin Paresthesia

	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	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	2	103	1.9% (0.0%, 4.5%)	4	142	2.7% (0.1%, 5.4%)
1 Year	2	97	1.9% (0.0%, 4.5%)	4	131	2.7% (0.1%, 5.4%)
2 Years	4	67	4.2% (0.1%, 8.3%)	6	92	4.4% (0.9%, 7.9%)
3 Years	4	49	4.2% (0.1%, 8.3%)	6	67	4.4% (0.9%, 7.9%)

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Table 20: Revision: Risk of First Occurrence of Skin Rash

	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	109	0.9% (0.0%, 2.7%)	1	156	0.6% (0.0%, 1.9%)
6 Months	1	104	0.9% (0.0%, 2.7%)	1	145	0.6% (0.0%, 1.9%)
1 Year	1	97	0.9% (0.0%, 2.7%)	1	132	0.6% (0.0%, 1.9%)
2 Years	1	69	0.9% (0.0%, 2.7%)	1	95	0.6% (0.0%, 1.9%)
3 Years	1	50	0.9% (0.0%, 2.7%).	1	69	0.6% (0.0%, 1.9%)

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Table 21: Revision: Risk of First Occurrence of Tissue or Skin Necrosis

	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	109	0.9% (0.0%, 2.7%)	1	156	0.6% (0.0%, 1.9%)
6 Months	1	104	0.9% (0.0%, 2.7%)	1	145	0.6% (0.0%, 1.9%)
1 Year	1	97	0.9% (0.0%, 2.7%)	1	132	0.6% (0.0%, 1.9%)
2 Years	1	69	0.9% (0.0%, 2.7%)	1	95	0.6% (0.0%, 1.9%)
3 Years	1	50	0.9% (0.0%, 2.7%)	1	69	0.6% (0.0%, 1.9%)

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Table 22: Revision: Risk of First Occurrence of Wrinkling

	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	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	3	102	2.9% (0.0%, 6.0%)	4	142	2.7% (0.1%, 5.4%)
1 Year	8	91	7.8% (2.6%, 13.0%)	11	124	7.7% (3.3%, 12.1%)
2 Years	13	60	13.2% (6.5%, 20.0%)	17	83	12.5% (6.9%, 18.2%)
3 Years	15	43	16.3% (8.6%, 24.0%)	19	61	14.7% (8.5%, 21.0%)

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Table 23: Revision: Risk of First Occurrence of Other Complications

	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	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	0	105	0.0% (0.0%, 0.0%)	0	146	0.0% (0.0%, 0.0%)
1 Year	0	98	0.0% (0.0%, 0.0%)	0	133	0.0% (0.0%, 0.0%)
2 Years	0	70	0.0% (0.0%, 0.0%)	0	96	0.0% (0.0%, 0.0%)
3 Years	0	51	0.0% (0.0%, 0.0%)	0	70	0.0% (0.0%, 0.0%)

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Table 24: Revision: Risk of First Occurrence of Implant 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	110	0.0% (0.0%, 0.0%)	0	157	0.0% (0.0%, 0.0%)
6 Months	2	105	1.8% (0.0%, 4.4%)	3	146	2.0% (0.0%, 4.2%)
1 Year	5	97	4.8% (0.7%, 8.9%)	7	133	4.8% (1.3%, 8.3%)
2 Years	12	71	12.5% (5.8%, 19.1%)	14	99	10.5% (5.2%, 15.7%)
3 Years	18	51	20.6% (11.9%, 29.3%)	24	70	20.4% (12.9%, 27.8%)

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Table 25: Revision: Risk of First Occurrence of a Secondary Procedure

	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	106	3.6% (0.1%, 7.1%)	4	153	2.5% (0.1%, 5.0%)
6 Months	8	99	7.3% (2.4%, 12.2%)	9	140	5.8% (2.1%, 9.5%)
1 Year	14	89	13.1% (6.7%, 19.6%)	16	125	10.8% (5.8%, 15.8%)
2 Years	23	63	22.7% (14.5%, 31.0%)	25	91	17.9% (11.4%, 24.3%)
3 Years	30	45	31.8% (22.1%, 41.4%)	36	64	28.4% (20.3%, 36.5%)