AR90 Clinical Study

Kaplan-Meier Risk Rates for Reconstruction

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Table 44: Risk of First Occurrence of Asymmetry

	By Patient		
	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)
4 Weeks	0	23	0.0% --
6 Months	2	21	8.7% (0.0, 20.2%)
1 Year	3	18	13.0% (0.0, 26.8%)
2 Years	3	15	13.0% (0.0, 26.8%)
3 Years	3	15	13.0% (0.0, 26.8%)
4 Years	3	14	13.0% (0.0, 26.8%)
5 Years	3	8	13.0% (0.0, 26.8%)

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Table 45: 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	2	21	8.7% (0.0%,20.2%)	2	30	6.3% (0.0%,14.6%)
6 Months	2	20	8.7% (0.0%,20.2%)	2	29	6.3% (0.0%,14.6%)
1 Year	2	18	8.7% (0.0%,20.2%)	2	26	6.3% (0.0%,14.6%)
2 Years	2	15	8.7% (0.0%,20.2%)	2	22	6.3% (0.0%,14.6%)
3 Years	2	15	8.7% (0.0%,20.2%)	2	22	6.3% (0.0%,14.6%)
4 Years	2	14	8.7% (0.0%,20.2%)	2	21	6.3% (0.0%,14.6%)
5 Years	2	8	8.7% (0.0%,20.2%)	2	12	6.3% (0.0%,14.6%)

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Table 46: 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	23	0.0% --	0	32	0.0% --
6 Months	1	21	4.3% (0.0%,12.7%)	1	30	3.1% (0.0%,9.2%)
1 Year	1	19	4.3% (0.0%,12.7%)	1	27	3.1% (0.0%,9.2%)
2 Years	1	16	4.3% (0.0%,12.7%)	1	23	3.1% (0.0%,9.2%)
3 Years	1	16	4.3% (0.0%,12.7%)	1	23	3.1% (0.0%,9.2%)
4 Years	1	15	4.3% (0.0%,12.7%)	1	22	3.1% (0.0%,9.2%)
5 Years	1	9	4.3% (0.0%,12.7%)	1	13	3.1% (0.0%,9.2%)

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Table 47: 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	23	0.0%	--	0	32	0.0%	--
6 Months	0	22	0.0%	--	0	31	0.0%	--
1 Year	0	20	0.0%	--	0	28	0.0%	--
2 Years	0	17	0.0%	--	0	24	0.0%	--
3 Years	0	17	0.0%	--	0	24	0.0%	--
4 Years	0	16	0.0%	--	0	23	0.0%	--
5 Years	0	10	0.0%	--	0	14	0.0%	--

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Table 48: 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	1	22	4.3% (0.0%,12.7%)	1	31	3.1% (0.0%,9.2%)
6 Months	1	21	4.3% (0.0%,12.7%)	1	30	3.1% (0.0%,9.2%)
1 Year	1	19	4.3% (0.0%,12.7%)	1	27	3.1% (0.0%,9.2%)
2 Years	1	16	4.3% (0.0%,12.7%)	1	23	3.1% (0.0%,9.2%)
3 Years	1	16	4.3% (0.0%,12.7%)	1	23	3.1% (0.0%,9.2%)
4 Years	1	15	4.3% (0.0%,12.7%)	1	22	3.1% (0.0%,9.2%)
5 Years	1	9	4.3% (0.0%,12.7%)	1	13	3.1% (0.0%,9.2%)

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Table 49: 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	23	0.0%	--	0	32	0.0%	--
6 Months	0	22	0.0%	--	0	31	0.0%	--
1 Year	0	20	0.0%	--	0	28	0.0%	--
2 Years	0	17	0.0%	--	0	24	0.0%	--
3 Years	0	17	0.0%	--	0	24	0.0%	--
4 Years	0	16	0.0%	--	0	23	0.0%	--
5 Years	0	10	0.0%	--	0	14	0.0%	--

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Table 50: 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	23	0.0% --	0	32	0.0% --
6 Months	3	20	13.0% (0.0%,26.8%)	3	29	9.4% (0.0%,19.5%)
1 Year	3	18	13.0% (0.0%,26.8%)	3	26	9.4% (0.0%,19.5%)
2 Years	3	16	13.0% (0.0%,26.8%)	3	23	9.4% (0.0%,19.5%)
3 Years	3	16	13.0% (0.0%,26.8%)	3	23	9.4% (0.0%,19.5%)
4 Years	3	15	13.0% (0.0%,26.8%)	3	22	9.4% (0.0%,19.5%)
5 Years	4	8	18.8% (1.9%,35.7%)	4	12	13.5% (1.0%,26.0%)

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Table 51: 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	23	0.0% --	0	32	0.0% --
6 Months	0	22	0.0% --	0	31	0.0% --
1 Year	0	20	0.0% --	0	28	0.0% --
2 Years	0	17	0.0% --	0	24	0.0% --
3 Years	0	17	0.0% --	0	24	0.0% --
4 Years	0	16	0.0% --	0	23	0.0% --
5 Years	1	9	7.7% (0.0%,22.2%)	1	13	5.6% (0.0%,16.1%)

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Table 52: 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	0	23	0.0%	--	0	32	0.0%	--
6 Months	0	22	0.0%	--	0	31	0.0%	--
1 Year	0	20	0.0%	--	0	28	0.0%	--
2 Years	0	17	0.0%	--	0	24	0.0%	--
3 Years	0	17	0.0%	--	0	24	0.0%	--
4 Years	0	16	0.0%	--	0	23	0.0%	--
5 Years	0	10	0.0%	--	0	14	0.0%	--

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Table 53: 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	0	23	0.0% --	0	32	0.0% --
6 Months	0	22	0.0% --	0	31	0.0% --
1 Year	0	20	0.0% --	0	28	0.0% --
2 Years	1	17	5.3% (0.0%,15.3%)	1	24	3.7% (0.0%,10.8%)
3 Years	2	16	10.8% (0.0%,25.0%)	2	23	7.7% (0.0%,18.0%)
4 Years	2	15	10.8% (0.0%,25.0%)	2	22	7.7% (0.0%,18.0%)
5 Years	2	10	10.8% (0.0%,25.0%)	2	14	7.7% (0.0%,18.0%)

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Table 54: 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	23	0.0% --	0	32	0.0% --
6 Months	1	21	4.3% (0.0%,12.7%)	1	30	3.1% (0.0%,9.2%)
1 Year	1	19	4.3% (0.0%,12.7%)	1	27	3.1% (0.0%,9.2%)
2 Years	1	17	4.3% (0.0%,12.7%)	1	24	3.1% (0.0%,9.2%)
3 Years	1	17	4.3% (0.0%,12.7%)	1	24	3.1% (0.0%,9.2%)
4 Years	1	16	4.3% (0.0%,12.7%)	1	23	3.1% (0.0%,9.2%)
5 Years	1	10	4.3% (0.0%,12.7%)	1	14	3.1% (0.0%,9.2%)

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Table 55: 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	23	0.0%	--	0	32	0.0%	--
6 Months	0	22	0.0%	--	0	31	0.0%	--
1 Year	0	20	0.0%	--	0	28	0.0%	--
2 Years	0	17	0.0%	--	0	24	0.0%	--
3 Years	0	17	0.0%	--	0	24	0.0%	--
4 Years	0	16	0.0%	--	0	23	0.0%	--
5 Years	0	10	0.0%	--	0	14	0.0%	--

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Table 56: 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	22	4.3% (0.0%,12.7%)	2	30	6.3% (0.0%,14.6%)
6 Months	1	21	4.3% (0.0%,12.7%)	2	29	6.3% (0.0%,14.6%)
1 Year	1	19	4.3% (0.0%,12.7%)	2	26	6.3% (0.0%,14.6%)
2 Years	1	17	4.3% (0.0%,12.7%)	2	24	6.3% (0.0%,14.6%)
3 Years	1	17	4.3% (0.0%,12.7%)	2	24	6.3% (0.0%,14.6%)
4 Years	1	16	4.3% (0.0%,12.7%)	2	23	6.3% (0.0%,14.6%)
5 Years	1	10	4.3% (0.0%,12.7%)	2	14	6.3% (0.0%,14.6%)

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Table 57: 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	23	0.0%	--	0	32	0.0%	--
6 Months	0	22	0.0%	--	0	31	0.0%	--
1 Year	0	20	0.0%	--	0	28	0.0%	--
2 Years	0	17	0.0%	--	0	24	0.0%	--
3 Years	0	17	0.0%	--	0	24	0.0%	--
4 Years	0	16	0.0%	--	0	23	0.0%	--
5 Years	0	10	0.0%	--	0	14	0.0%	--

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Table 58: Risk of First Occurrence of Scarring 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	0	23	0.0% --	0	32	0.0% --
6 Months	1	21	4.5% (0.0%,13.2%)	2	29	6.5% (0.0%,15.1%)
1 Year	2	18	9.3% (0.0%,21.6%)	3	25	9.9% (0.0%,20.6%)
2 Years	2	15	9.3% (0.0%,21.6%)	3	21	9.9% (0.0%,20.6%)
3 Years	2	15	9.3% (0.0%,21.6%)	3	21	9.9% (0.0%,20.6%)
4 Years	2	14	9.3% (0.0%,21.6%)	3	20	9.9% (0.0%,20.6%)
5 Years	2	9	9.3% (0.0%,21.6%)	3	12	9.9% (0.0%,20.6%)

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Table 59: 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	0	23	0.0%	--	0	32	0.0%	--
6 Months	0	22	0.0%	--	0	31	0.0%	--
1 Year	0	20	0.0%	--	0	28	0.0%	--
2 Years	0	17	0.0%	--	0	24	0.0%	--
3 Years	0	17	0.0%	--	0	24	0.0%	--
4 Years	0	16	0.0%	--	0	23	0.0%	--
5 Years	0	10	0.0%	--	0	14	0.0%	--

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Table 60: 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	1	22	4.3% (0.0%,12.7%)	2	30	6.3% (0.0%,14.6%)
6 Months	1	21	4.3% (0.0%,12.7%)	2	29	6.3% (0.0%,14.6%)
1 Year	2	18	9.4% (0.0%,21.8%)	3	25	9.9% (0.0%,20.5%)
2 Years	2	16	9.4% (0.0%,21.8%)	3	22	9.9% (0.0%,20.5%)
3 Years	2	16	9.4% (0.0%,21.8%)	3	22	9.9% (0.0%,20.5%)
4 Years	2	15	9.4% (0.0%,21.8%)	3	21	9.9% (0.0%,20.5%)
5 Years	2	9	9.4% (0.0%,21.8%)	3	12	9.9% (0.0%,20.5%)

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Table 61: 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	22	4.3% (0.0%,12.7%)	1	31	3.1% (0.0%,9.2%)
6 Months	1	22	4.3% (0.0%,12.7%)	1	31	3.1% (0.0%,9.2%)
1 Year	1	20	4.3% (0.0%,12.7%)	1	28	3.1% (0.0%,9.2%)
2 Years	1	17	4.3% (0.0%,12.7%)	1	24	3.1% (0.0%,9.2%)
3 Years	2	16	10.0% (0.0%,23.2%)	2	23	7.2% (0.0%,16.8%)
4 Years	2	15	10.0% (0.0%,23.2%)	3	21	11.2% (0.0%,23.3%)
5 Years	2	10	10.0% (0.0%,23.2%)	3	14	11.2% (0.0%,23.3%)

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Table 62: 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	0	23	0.0% --	0	32	0.0% --
6 Months	1	21	4.5% (0.0%,13.2%)	0	31	0.0% (0.0%,0.0%)
1 Year	1	19	4.5% (0.0%,13.2%)	0	28	0.0% (0.0%,0.0%)
2 Years	1	16	4.5% (0.0%,13.2%)	0	24	0.0% (0.0%,0.0%)
3 Years	1	16	4.5% (0.0%,13.2%)	0	24	0.0% (0.0%,0.0%)
4 Years	1	15	4.5% (0.0%,13.2%)	0	23	0.0% (0.0%,0.0%)
5 Years	1	9	4.5% (0.0%,13.2%)	0	14	0.0% (0.0%,0.0%)

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Table 63: 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	23	0.0% --	0	32	0.0% --
6 Months	1	21	4.5% (0.0%,13.2%)	1	30	3.2% (0.0%,9.4%)
1 Year	3	17	14.1% (0.0%,28.9%)	3	25	10.1% (0.0%,21.0%)
2 Years	4	13	19.5% (2.2%,36.7%)	4	20	13.9% (1.2%,26.6%)
3 Years	4	13	19.5% (2.2%,36.7%)	4	20	13.9% (1.2%,26.6%)
4 Years	5	11	26.2% (6.0%,46.4%)	6	17	22.9% (6.5%,39.4%)
5 Years	6	5	35.4% (10.9%,59.9%)	7	9	29.4% (10.1%,48.7%)

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Table 64: 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	23	0.0%	--	0	32	0.0%	--
6 Months	0	22	0.0%	--	0	31	0.0%	--
1 Year	0	20	0.0%	--	0	28	0.0%	--
2 Years	0	17	0.0%	--	0	24	0.0%	--
3 Years	0	17	0.0%	--	0	24	0.0%	--
4 Years	0	16	0.0%	--	0	23	0.0%	--
5 Years	0	10	0.0%	--	0	14	0.0%	--