AR90 Clinical Study

Kaplan-Meier Risk Rates for Augmentation

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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	5	183	2.6% (0.4, 4.9%)
6 Months	7	175	3.7% (1.0, 6.4%)
1 Year	11	165	5.9% (2.5, 9.3%)
2 Years	13	148	7.2% (3.4, 11.0%)
3 Years	19	134	11.1% (6.4, 15.8%)
4 Years	21	118	12.5% (7.5, 17.6%)
5 Years	24	67	15.3% (9.5, 21.1%)

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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	13	174	6.8% (3.2%,10.4%)	23	348	6.1% (3.7%,8.5%)
6 Months	20	160	10.6% (6.2%,15.0%)	32	325	8.5% (5.7%,11.4%)
1 Year	26	151	14.0% (9.0%,19.0%)	40	309	10.8% (7.6%,14.0%)
2 Years	30	129	16.5% (11.1%,21.9%)	45	268	12.4% (9.0%,15.8%)
3 Years	34	117	19.2% (13.3%,25.0%)	53	242	15.1% (11.3%,18.9%)
4 Years	37	101	21.4% (15.2%,27.5%)	55	213	15.9% (12.0%,19.8%)
5 Years	42	54	25.8% (18.8%,32.7%)	62	117	19.2% (14.7%,23.6%)

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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	187	0.0% --	0	371	0.0% --
6 Months	0	180	0.0% --	0	357	0.0% --
1 Year	0	174	0.0% --	0	345	0.0% --
2 Years	2	152	1.3% (0.0%,3.0%)	3	302	1.0% (0.0%,2.1%)
3 Years	2	142	1.3% (0.0%,3.0%)	3	281	1.0% (0.0%,2.1%)
4 Years	4	125	2.8% (0.1%,5.4%)	7	247	2.5% (0.7%,4.3%)
5 Years	4	74	2.8% (0.1%,5.4%)	7	145	2.5% (0.7%,4.3%)

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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	1	186	0.5% (0.0%,1.6%)	1	370	0.3% (0.0%,0.8%)
6 Months	1	179	0.5% (0.0%,1.6%)	1	356	0.3% (0.0%,0.8%)
1 Year	1	173	0.5% (0.0%,1.6%)	1	344	0.3% (0.0%,0.8%)
2 Years	1	153	0.5% (0.0%,1.6%)	1	304	0.3% (0.0%,0.8%)
3 Years	1	142	0.5% (0.0%,1.6%)	1	282	0.3% (0.0%,0.8%)
4 Years	2	126	1.3% (0.0%,3.0%)	2	251	0.6% (0.0%,1.5%)
5 Years	2	75	1.3% (0.0%,3.0%)	2	148	0.6% (0.0%,1.5%)

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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	3	184	1.6% (0.0%,3.4%)	3	368	0.8% (0.0%,1.7%)
6 Months	5	175	2.7% (0.4%,4.9%)	5	352	1.3% (0.2%,2.5%)
1 Year	5	170	2.7% (0.4%,4.9%)	5	341	1.3% (0.2%,2.5%)
2 Years	5	151	2.7% (0.4%,4.9%)	5	302	1.3% (0.2%,2.5%)
3 Years	5	140	2.7% (0.4%,4.9%)	5	280	1.3% (0.2%,2.5%)
4 Years	6	124	3.4% (0.7%,6.1%)	6	249	1.7% (0.3%,3.1%)
5 Years	6	74	3.4% (0.7%,6.1%)	6	147	1.7% (0.3%,3.1%)

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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	187	0.0%	--	0	371	0.0%	--
6 Months	0	180	0.0%	--	0	357	0.0%	--
1 Year	0	174	0.0%	--	0	345	0.0%	--
2 Years	0	154	0.0%	--	0	305	0.0%	--
3 Years	0	143	0.0%	--	0	283	0.0%	--
4 Years	0	128	0.0%	--	0	253	0.0%	--
5 Years	0	76	0.0%	--	0	149	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	1	187	0.5% (0.0%,1.6%)	1	371	0.3% (0.0%,0.8%)
6 Months	6	175	3.2% (0.7%,5.8%)	7	351	1.9% (0.5%,3.3%)
1 Year	8	167	4.4% (1.4%,7.3%)	9	337	2.5% (0.9%,4.1%)
2 Years	10	149	5.6% (2.2%,8.9%)	11	299	3.1% (1.3%,4.9%)
3 Years	11	137	6.2% (2.6%,9.7%)	13	275	3.7% (1.7%,5.7%)
4 Years	12	123	6.9% (3.1%,10.7%)	14	246	4.1% (2.0%,6.2%)
5 Years	12	74	6.9% (3.1%,10.7%)	14	145	4.1% (2.0%,6.2%)

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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	4	183	2.1% (0.1%,4.1%)	7	364	1.9% (0.5%,3.2%)
6 Months	18	163	9.7% (5.4%,13.9%)	31	328	8.4% (5.6%,11.2%)
1 Year	23	153	12.5% (7.7%,17.2%)	38	311	10.4% (7.3%,13.5%)
2 Years	25	131	13.8% (8.7%,18.8%)	44	265	12.3% (8.9%,15.8%)
3 Years	32	114	18.6% (12.7%,24.5%)	54	235	15.8% (11.9%,19.7%)
4 Years	37	98	22.4% (15.9%,28.9%)	61	205	18.5% (14.2%,22.8%)
5 Years	38	54	23.3% (16.7%,30.0%)	64	115	20.0% (15.5%,24.5%)

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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	187	0.0% --	0	371	0.0% --
6 Months	2	178	1.1% (0.0%,2.5%)	3	354	0.8% (0.0%,1.7%)
1 Year	2	172	1.1% (0.0%,2.5%)	3	342	0.8% (0.0%,1.7%)
2 Years	2	152	1.1% (0.0%,2.5%)	3	302	0.8% (0.0%,1.7%)
3 Years	2	141	1.1% (0.0%,2.5%)	3	280	0.8% (0.0%,1.7%)
4 Years	2	126	1.1% (0.0%,2.5%)	3	250	0.8% (0.0%,1.7%)
5 Years	2	74	1.1% (0.0%,2.5%)	3	146	0.8% (0.0%,1.7%)

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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	4	183	2.1% (0.1%,4.1%)	6	365	1.6% (0.3%,2.8%)
6 Months	7	173	3.7% (1.0%,6.4%)	10	347	2.7% (1.0%,4.3%)
1 Year	7	167	3.7% (1.0%,6.4%)	10	335	2.7% (1.0%,4.3%)
2 Years	8	149	4.3% (1.4%,7.3%)	11	299	3.0% (1.2%,4.7%)
3 Years	9	138	5.0% (1.8%,8.2%)	12	277	3.3% (1.5%,5.2%)
4 Years	9	123	5.0% (1.8%,8.2%)	12	247	3.3% (1.5%,5.2%)
5 Years	9	71	5.0% (1.8%,8.2%)	12	143	3.3% (1.5%,5.2%)

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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	11	176	5.7% (2.4%,9.0%)	16	355	4.2% (2.2%,6.2%)
6 Months	18	163	9.5% (5.3%,13.7%)	29	330	7.8% (5.0%,10.5%)
1 Year	22	154	11.8% (7.1%,16.4%)	35	314	9.4% (6.5%,12.4%)
2 Years	24	134	13.0% (8.1%,17.8%)	38	275	10.3% (7.2%,13.5%)
3 Years	27	123	15.0% (9.7%,20.3%)	44	251	12.4% (8.9%,15.9%)
4 Years	30	106	17.2% (11.5%,22.9%)	48	219	13.9% (10.2%,17.6%)
5 Years	30	64	17.2% (11.5%,22.9%)	49	129	14.3% (10.5%,18.1%)

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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	187	0.0% --	0	371	0.0% --
6 Months	1	179	0.6% (0.0%,1.6%)	1	356	0.3% (0.0%,0.8%)
1 Year	2	172	1.1% (0.0%,2.6%)	2	343	0.6% (0.0%,1.3%)
2 Years	2	152	1.1% (0.0%,2.6%)	2	303	0.6% (0.0%,1.3%)
3 Years	2	141	1.1% (0.0%,2.6%)	2	281	0.6% (0.0%,1.3%)
4 Years	4	125	2.6% (0.1%,5.1%)	6	249	2.1% (0.4%,3.7%)
5 Years	4	75	2.6% (0.1%,5.1%)	6	148	2.1% (0.4%,3.7%)

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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	13	174	6.8% (3.2%,10.4%)	23	348	6.1% (3.7%,8.5%)
6 Months	21	159	11.2% (6.7%,15.7%)	37	320	9.9% (6.9%,13.0%)
1 Year	29	145	15.7% (10.5%,21.0%)	51	294	13.9% (10.4%,17.5%)
2 Years	30	128	16.3% (11.0%,21.7%)	53	259	14.5% (10.9%,18.2%)
3 Years	32	116	17.7% (12.1%,23.3%)	58	234	16.3% (12.4%,20.2%)
4 Years	34	101	19.2% (13.4%,25.1%)	61	204	17.5% (13.4%,21.5%)
5 Years	35	61	20.2% (14.1%,26.3%)	62	122	17.9% (13.8%,22.0%)

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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	187	0.0%	--	0	371	0.0%	--
6 Months	0	180	0.0%	--	0	357	0.0%	--
1 Year	0	174	0.0%	--	0	345	0.0%	--
2 Years	0	154	0.0%	--	0	305	0.0%	--
3 Years	0	143	0.0%	--	0	283	0.0%	--
4 Years	0	128	0.0%	--	0	253	0.0%	--
5 Years	0	76	0.0%	--	0	149	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	2	185	1.0% (0.0%,2.5%)	3	368	0.8% (0.0%,1.7%)
6 Months	4	176	2.1% (0.1%,4.2%)	6	351	1.6% (0.3%,2.9%)
1 Year	10	164	5.5% (2.2%,8.9%)	12	333	3.3% (1.5%,5.2%)
2 Years	12	142	6.8% (3.1%,10.5%)	14	291	4.0% (1.9%,6.0%)
3 Years	14	129	8.2% (4.0%,12.3%)	16	267	4.7% (2.4%,6.9%)
4 Years	14	114	8.2% (4.0%,12.3%)	17	236	5.0% (2.7%,7.4%)
5 Years	14	68	8.2% (4.0%,12.3%)	17	141	5.0% (2.7%,7.4%)

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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	8	179	4.2% (1.3%,7.0%)	13	358	3.4% (1.6%,5.3%)
6 Months	9	171	4.7% (1.7%,7.7%)	14	343	3.7% (1.8%,5.6%)
1 Year	9	165	4.7% (1.7%,7.7%)	14	331	3.7% (1.8%,5.6%)
2 Years	9	147	4.7% (1.7%,7.7%)	14	293	3.7% (1.8%,5.6%)
3 Years	9	136	4.7% (1.7%,7.7%)	14	271	3.7% (1.8%,5.6%)
4 Years	11	122	6.2% (2.6%,9.8%)	16	244	4.4% (2.3%,6.6%)
5 Years	11	73	6.2% (2.6%,9.8%)	16	144	4.4% (2.3%,6.6%)

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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	4	183	2.1% (0.1%,4.1%)	6	365	1.6% (0.3%,2.8%)
6 Months	10	171	5.4% (2.1%,8.6%)	19	340	5.1% (2.9%,7.4%)
1 Year	18	157	9.9% (5.6%,14.3%)	30	317	8.3% (5.5%,11.1%)
2 Years	23	133	12.9% (8.0%,17.9%)	39	270	11.0% (7.8%,14.3%)
3 Years	23	122	12.9% (8.0%,17.9%)	40	247	11.4% (8.0%,14.7%)
4 Years	26	106	15.2% (9.7%,20.6%)	43	218	12.5% (9.0%,16.0%)
5 Years	26	62	15.2% (9.7%,20.6%)	43	126	12.5% (9.0%,16.0%)

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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	0	187	0.0% --	0	371	0.0% --
6 Months	1	179	0.5% (0.0%,1.6%)	2	355	0.6% (0.0%,1.3%)
1 Year	2	172	1.1% (0.0%,2.6%)	4	341	1.1% (0.0%,2.2%)
2 Years	3	152	1.7% (0.0%,3.7%)	6	301	1.7% (0.4%,3.1%)
3 Years	4	140	2.4% (0.1%,4.7%)	8	277	2.4% (0.8%,4.1%)
4 Years	4	125	2.4% (0.1%,4.7%)	8	247	2.4% (0.8%,4.1%)
5 Years	4	73	2.4% (0.1%,4.7%)	8	143	2.4% (0.8%,4.1%)

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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	187	0.0%	--	0	371	0.0%	--
6 Months	0	180	0.0%	--	0	357	0.0%	--
1 Year	0	174	0.0%	--	0	345	0.0%	--
2 Years	0	154	0.0%	--	0	305	0.0%	--
3 Years	0	143	0.0%	--	0	283	0.0%	--
4 Years	0	128	0.0%	--	0	253	0.0%	--
5 Years	0	76	0.0%	--	0	149	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	2	185	1.1% (0.0%,2.5%)	4	367	1.1% (0.0%,2.1%)
6 Months	7	174	3.8% (1.0%,6.5%)	11	348	3.0% (1.2%,4.7%)
1 Year	10	165	5.4% (2.2%,8.7%)	16	331	4.4% (2.3%,6.5%)
2 Years	17	138	9.9% (5.4%,14.4%)	28	279	8.2% (5.3%,11.2%)
3 Years	19	126	11.3% (6.5%,16.1%)	31	256	9.3% (6.1%,12.4%)
4 Years	21	111	12.8% (7.6%,18.0%)	36	224	11.2% (7.7%,14.7%)
5 Years	21	65	12.8% (7.6%,18.0%)	37	131	11.6% (8.1%,15.2%)

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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	187	0.0%	--	0	371	0.0%	--
6 Months	0	180	0.0%	--	0	357	0.0%	--
1 Year	0	174	0.0%	--	0	345	0.0%	--
2 Years	0	154	0.0%	--	0	305	0.0%	--
3 Years	0	143	0.0%	--	0	283	0.0%	--
4 Years	0	128	0.0%	--	0	253	0.0%	--
5 Years	0	76	0.0%	--	0	149	0.0%	--