

Inamed Corporation
PMA P020056
McGhan Silicone-Filled Breast Implants

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Parallel Analysis of A95/R95 and Adjunct Revision Patients

ADJUNCT STUDY - REVISION

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3-Year Complication Rates for Revision Patients in Adjunct Study and 1995 Saline Study

Complication	Adjunct 3-Year Risk By Patient	A95/R95 3-Year Risk By Patient
Reoperation	34.5% (31.9%, 37.0%)	31.8% (22.1%, 41.4%)
Implant Replacement/Removal	24.1% (21.7%, 26.5%)	20.6% (11.9%, 29.3%)
Capsular Contracture	20.0% (17.6%, 22.3%)	17.9% (10.0%, 25.7%)
Implant Palpability/Visibility	13.6% (11.4%, 15.8%)	19.5% (10.5%, 28.5%)
Wrinkling	10.6% (8.7%, 12.5%)	16.3% (8.6%, 24.0%)
Asymmetry	9.8% (7.9%, 11.6%)	18.6% (10.1%, 27.2%)
Breast Pain	7.8% (6.1%, 9.4%)	18.4% (10.5%, 26.3%)
Implant Malposition	7.3% (5.6%, 8.9%)	13.1% (5.6%, 20.5%)
Loss of Nipple Sensation	3.7% (2.5%, 4.8%)	0.9% (0.0%, 2.8%)
Capsule Calcification	3.4% (2.3%, 4.5%)	5.7% (0.0%, 11.3%)
Implant Rupture/Deflation	2.7% (1.4%, 3.9%)	12.1% (5.0%, 19.2%)
Hypertrophic Scarring	2.0% (1.3%, 2.7%)	2.0% (0.0%, 4.8%)
Swelling	1.9% (1.4%, 2.5%)	N/A
Nipple Hypersensitivity	1.9% (1.1%, 2.7%)	N/A
Skin Paresthesia	1.4% (0.8%, 2.1%)	4.2% (0.1%, 8.3%)
Nipple Paresthesia	1.1% (0.4%, 1.9%)	4.1% (0.1%, 8.0%)
Redness	1.0% (0.6%, 1.5%)	N/A
Other Complications	1.0% (0.5%, 1.5%)	0.0% (0.0%, 0.0%)
Skin Hypersensitivity	0.7% (0.2%, 1.3%)	N/A
Infection	0.7% (0.3%, 1.2%)	2.8% (0.0%, 6.0%)
Bruising	0.7% (0.4%, 1.1%)	N/A
Skin Rash	0.6% (0.0%, 1.3%)	0.9% (0.0%, 2.7%)
Delayed Wound Healing	0.6% (0.2%, 1.1%)	0.9% (0.0%, 2.7%)
Implant Extrusion	0.6% (0.3%, 1.0%)	0.0% (0.0%, 0.0%)
Seroma	0.5% (0.1%, 0.9%)	1.8% (0.0%, 4.3%)
Hematoma	0.5% (0.2%, 0.8%)	3.6% (0.1%, 7.1%)
Pneumothorax	0.5% (0.2%, 0.8%)	0.0% (0.0%, 0.0%)
Irritation	0.4% (0.1%, 0.8%)	1.9% (0.0%, 4.6%)
Lymphadenopathy	0.3% (0.0%, 0.6%)	0.0% (0.0%, 0.0%)
Tissue or Skin Necrosis	0.2% (0.0%, 0.6%)	0.9% (0.0%, 2.7%)