

MemoryGel™ Breast Implant

hot topics

MEMORYGEL™ BREAST IMPLANT 6-YEAR CORE DATA

In November 2008, Mentor reported to FDA the MemoryGel™ Breast Implant Core Study 6-year data. Allergan's Natrelle™ Core Breast Implant 6-year data was reported in the Journal of Plastic and Reconstructive Surgery supplemental edition. Data showing the reported incidence of two key complication rates, rupture and capsular contracture, for the augmentation and reconstruction study cohorts, are provided below. It should be noted that the Mentor data and the Allergan data, set forth below, are not from head to head clinical studies and there may be differences in protocol design.

MENTOR* MEMORYGEL™ BREAST IMPLANT 6-YEAR CORE DATA		
	Rupture Rate	Capsular Contracture III/IV
Augmentation (Primary)	1.1% (0.3-4.3) N=552	9.8% (7.6-12.7) N=552
Reconstruction (Primary)	3.8% (1.4-9.8) N=251	13.7% (9.7-19.1) N=251

ALLERGAN** SILICONE NATRELLE™ BREAST IMPLANT 6-YEAR CORE DATA		
	Rupture Rate	Capsular Contracture III/IV
Augmentation (Primary)	5.5% (2.8-10.7) N=455	14.8% (11.7-18.5) N=455
Reconstruction (Primary)	9.3% (3.6-22.9) N=98	15.9% (9.7-25.6) N=98

*Mentor 6-Year Data Core Gel Clinical Study Annual Report, Submitted November 2008 to FDA

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