

Kline, Cliff

From: Free, Donna
Sent: Monday, December 20, 2004 3:11 PM
To: Kline, Cliff
Subject: FW: Complication Comparison Table

-----Original Message-----

From: Allen, Samie Niver [mailto: SXN@CDRH.FDA.GOV]
Sent: Monday, December 20, 2004 3:02 PM
To: 'Free, Donna'
Subject: FW: Complication Comparison Table

-----Original Message-----

From: Free, Donna [mailto: DFree@mentorcorp.com]
Sent: Monday, October 04, 2004 7:35 PM
To: 'Lerner, Herbert P.'
Cc: 'Allen, Samie Niver'; Michael, Maher
Subject: Complication Comparison Table

Hi Herb,

Attached please find the Complication Comparison Table you requested. The table separately delineates Mentor's 2 and 3-Year complication rates in portrait format. Please let us know if you need anything else

Thanks

Donna

2005 4/10/12 2:50 PM A-McMILLAN

Comparison of Mentor Core Two Year and Three Year Complication* Rates

Complication	Augmentation		Reconstruction		Revision	
	Risk by Pt% (95% CI) 2-Year	Risk by Pt% (95% CI) 3-Year	Risk by Pt% (95% CI) 2-Year	Risk by Pt% (95% CI) 3-Year	Risk by Pt% (95% CI) 2-Year	Risk by Pt% (95% CI) 3-Year
Breast mass	0.8 (0.0, 1.5)	2.4 (1.0, 3.7)	2.2 (0.3, 4.0)	3.9 (1.1, 6.6)	3.5 (1.0, 6.1)	5.8 (2.5, 9.1)
Capsular contracture	7.9 (5.6, 10.2)	8.2 (5.9, 10.6)	7.3 (3.9, 10.7)	8.8 (4.9, 12.7)	16.3 (11.1, 21.4)	17.2 (11.9, 22.4)
Granuloma	0.2 (0.0, 0.5)	0.2 (0.0, 0.5)	0 -	0 -	1.0 (0.2, 4)	1.0 (0.2, 3)
Hematoma	2.6 (1.2, 3.9)	2.6 (1.2, 3.9)	0.8 (0.0, 1.9)	1.5 (0.3, 3)	3.0 (0.6, 5.4)	3.0 (0.6, 5.3)
Hypertrophic scarring	6.1 (4.1, 8.2)	6.2 (4.2, 8.3)	3.9 (1.0, 6.8)	6.4 (3.0, 9.8)	5.7 (2.4, 8.9)	6.0 (2.7, 9.3)
Implant extrusion	0 -	0 -	1.6 (0.1, 3.2)	1.2 (0.2, 6)	1.5 (0.0, 3.2)	1.5 (0.0, 3.1)
Implant removal with and without Replacement	3.6 (1.9, 5.0)	5.1 (3.2, 7.1)	11.4 (7.4, 15.4)	13.3 (8.8, 17.8)	9.2 (4.9, 13.5)	13.3 (8.4, 18.2)
Infection	1.5 (0.5, 2.5)	1.5 (0.5, 2.5)	5.3 (2.5, 8.2)	5.3 (2.5, 8.1)	1.0 (0.0, 2.5)	1.0 (0.2, 4)
Inflammation	0.4 (0.0, 0.9)	0.4 (0.0, 0.9)	0 -	0 -	1.5 (0.3, 2)	1.5 (0.3, 2)
Miscarriage	1.1 (0.2, 2.0)	1.4 (0.4, 2.4)	0.9 (0.2, 0)	0.9 (0.2, 2.0)	0 -	0 -
New diagnosis of rheumatic disease	0.4 (0.0, 1.0)	0.6 (0.0, 1.2)	0 -	0.4 (0.0, 1.2)	1.0 (0.2, 4)	1.0 (0.2, 4)
Nipple sensation changes	NA**	10.8 (8.1, 13.4)	NA	3.1 (0.6, 6.3)	NA	8.6 (4.7, 12.6)
Nipple hypersensitivity	6.1 (4.1, 8.1)	NA	1.7 (0.1, 3.3)	NA	6.1 (2.8, 9.5)	NA
Ptosis	2.1 (0.8, 3.3)	2.2 (0.9, 3.4)	3.6 (0.0, 7.4)	6.9 (2.1, 11.8)	2.7 (0.0, 5.5)	2.2 (0.0, 4.3)
Recurrent breast cancer	0 -	0 -	1.3 (0.2, 8)	1.7 (0.0, 3.4)	0.5 (0.1, 5)	0.5 (0.1, 5)
Reoperation	12.1 (9.4, 14.9)	15.0 (11.9, 18.0)	25.2 (19.8, 30.6)	26.3 (21.7, 31.9)	21.1 (15.4, 26.7)	26.3 (20.0, 32.6)
Rupture	0 -	0.2 (0.0, 0.7)	0 -	0.6 (0.0, 1.8)	0 -	2.5 (0.0, 4.9)
Seroma	0.9 (0.1, 1.7)	0.9 (0.1, 1.7)	4.4 (1.9, 6.9)	4.9 (2.2, 7.6)	2.0 (0.1, 3.9)	2.0 (0.0, 3.9)

* Complications are listed if the rate is $\geq 1\%$. Excludes mild occurrences of asymmetry, breast pain, calcification, position change, nipple sensation changes, nipple complications, and wrinkling.

** Based on input from FDA, "Nipple sensation changes" which was not a complication category in the PMA submitted in December 2003, was added for the 2004 update. Hence the NA in the 2-Year cells, indicating the data were not analyzed by that complication. Conversely, "Nipple hypersensitivity," which was a complication category reported in the PMA, was not a category in the 2004 update, hence the NA in the 2004 cells