Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 11.9

INCIDENCE OF PATIENT REPORT OF POSTOPERATIVE RHEUMATOLOGICAL SYMPTOMS - FDA Item 8

		12 Months		24 Months		36 Months	
Symptom Type	Baseline	Yes	No	Yes	No	Yes	No
LOSS OF WEIGHT WITHOUT DIETING	Yes	1	3	1	3	0	2
	No	0	835	2	798	1	574
FATIGUE	Yes	7	5	5	4	1	1
	No	6	835	14	798	6	574
INSOMNIA	Yes	12	18	8	20	2	13
	No	4	835	9	798	2	574
WEAKNESS	Yes	1	0	1	0	0	0
	No	2	835	6	798	2	574
EXHAUSTION	Yes	1	0	1	0	0	0
	No	1	835	9	798	3	574
JOINT SWELLING	Yes	4	4	4	4	0	2
	No	3	835	7	798	4	574
HEEL PAIN	Yes	2	1	0	2	1	0
	No	2	835	6	798	2	574
FREQUENT MUSCLE CRAMPS	Yes	2	2	2	2	0	1
	No	4	835	9	798	4	574
NUMBNESS OF FEET	Yes	1	2	1	2	0	1
	No	1	835	7	798	2	574
RINGING IN EARS	Yes	6	8	4	9	2	5

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Note: The visits reflect the visit name on the case report form.

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Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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		12 Months		24 Months		36 Months	
Symptom Type	Baseline	Yes	No	Yes	No	Yes	No
RINGING IN EARS	No	3	835	7	798	4	574
PAIN/GRITTINESS IN EYES	No	2	835	2	798	1	574
DRYNESS OF EYES/NOSE	Yes	9	8	8	8	2	8
	No	0	835	1	798	1	574
PAIN ON SWALLOWING OR CHEWING	Yes	1	0	1	0	0	0
	No	0	835	2	798	0	574
NECK PAIN/STIFFNESS	Yes	9	12	6	12	3	12
	No	4	835	6	798	6	574
PAIN ON BREATHING	No	0	835	1	798	0	574
HEART MURMURS	Yes	15	22	13	22	3	17
	No	1	835	1	798	1	574
LOSS OF APPETITE	Yes	1	0	1	0	0	0
	No	0	835	3	798	0	574
PERSISTENT FEVER	No	0	835	0	798	0	574
NIGHT SWEATS	Yes	8	13	6	13	1	6
	No	5	835	6	798	4	574
GENERALIZED ACHING	Yes	5	4	6	4	1	3
	No	1	835	8	798	4	574

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		12 Months		24 Months		36 Months	
Symptom Type	Baseline	Yes	No	Yes	No	Yes	No
LOSS OF HEIGHT	Yes	2	2	2	2	0	1
	No	0	835	2	798	0	574
JOINT PAIN	Yes	9	9	9	9	2	4
	No	9	835	18	798	12	574
FREQUENT MUSCLE PAIN	Yes	4	3	2	2	0	3
	No	3	835	5	798	1	574
NUMBNESS OF HANDS	Yes	4	7	3	8	4	6
	No	4	835	12	798	5	574
JAW PAIN	Yes	3	4	3	4	1	3
	No	0	835	0	798	0	574
OPEN SORES	No	0	835	0	798	0	574
REDNESS OF EYES	Yes	3	0	3	0	1	1
	No	0	835	1	798	1	574
DRYNESS OF MOUTH	Yes	1	3	1	2	1	2
	No	1	835	2	798	2	574
BACK PAIN/STIFFNESS	Yes	11	13	10	12	2	9
	No	5	835	12	798	4	574
SEVERE CHEST PAINS	No	1	835	2	798	0	574

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		12 Months		24 Months		36 Months	
Symptom Type	Baseline	Yes	No	Yes	No	Yes	No
CHRONIC COUGH	Yes	0	1	0	1	0	1
	No	0	835	2	798	0	574
DIFFICULTY SWALLOWING	No	0	835	2	798	0	574
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	Yes	4	5	4	5	2	4
	No	2	835	2	798	2	574
SEVERE RASHES	No	1	835	2	798	0	574
SEVERE DRYNESS OF SKIN	Yes	1	1	2	1	1	0
	No	3	835	1	798	2	574
TENDER LUMPS/BUMPS	Yes	1	1	1	1	0	0
	No	1	835	4	798	1	574
EXCESSIVE SENSITIVITY TO SUN	Yes	2	1	2	1	2	1
	No	0	835	1	798	0	574
COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE	Yes	8	9	8	9	6	8
	No	1	835	1	798	1	574
FREQUENT HIVES	Yes	0	1	0	0	0	0
	No	0	835	1	798	0	574
TIGHTNESS OF SKIN	Yes	0	1	0	1	0	0
	No	0	835	0	798	0	574

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		12 Months		24 Months		36 Months	
Symptom Type	Baseline	Yes	No	Yes	No	Yes	No
UNUSUAL HAIR LOSS	Yes	3	3	3	3	1	2
	No	1	835	1	798	4	574
TENDERNESS OF SCALP	Yes	0	1	0	1	0	1
	No	0	835	0	798	0	574
SEVERE BRUISING WITH LITTLE OR NO INJURY	Yes	4	5	4	7	1	3
	No	2	835	3	798	3	574

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