

**Kline, Cliff**

**From:** Free, Donna  
**Sent:** Friday, December 17, 2004 2:45 PM  
**To:** 'Dawisha, Sahar'  
**Cc:** Allen, Samie Niver; Silverman, Phyllis M.; Michael, Maher; Kline, Cliff  
**Subject:** FW: CTD issues

Hi Sahar,

Please see our responses and the update of the tables you requested.

Have a great weekend!

Donna

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

**From:** Kline, Cliff  
**Sent:** Friday, December 17, 2004 11:07 AM  
**To:** Free, Donna  
**Subject:** RE: CTD issues

**Could you incorporate the rheumatologic physical exam findings into the symptom categories and re-do the following:**

**1. All tables summarizing the symptom categories (e.g. Tables 11.2, 11.6 were the ones I could easily find).**

1 Response:

Physical exam findings have been incorporated into all tables summarizing symptom categories (Tables 11.2, 11.3, and 11.7). The new column header is entitled "sign/symptom."

**2. All statistical analyses/comparisons involving symptom categories (i.e. Table 11.10).**

2 Response:

Table 11.10 compares Saline Prospective Study (SPS) symptom category results to those of the Core Study. This table has been updated by incorporating physical exam findings into symptom categories.

**3. Compare the rheumatologic physical exam findings between the SPS and Core Gel (i.e. 11.11).**

3 Response:

Table 11.11 compares SPS signs/symptoms results to those of the Core Study. This table has been updated by incorporating physical exam findings with the symptoms.

**4. Include the rheumatologic physical exam findings into the combined fatigue, combined pain, and combined fibro (as requested in deficiency 7.b.) and compare this to SPS.**

4 Response:

All 11.x tables have been updated to include the physical exam findings into the combined fields of fatigue, pain, and fibromyalgia.

**5. Include the rheumatologic physical exam findings into the symptom categories and**

perform the GEE analysis for age.

5 Response:

Table 11.2 has been updated to incorporate physical exam findings into the symptom categories.

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

**From:** Free, Donna

**Sent:** Wednesday, December 08, 2004 8:07 AM

**To:** Kline, Cliff

**Subject:** FW: CTD issues

Cliff,

Please review and provide responses.

Thanks

Donna

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

**From:** Dawisha, Sahar [mailto:SXD@CDRH.FDA.GOV]

**Sent:** Wednesday, December 08, 2004 7:10 AM

**To:** 'Free, Donna'

**Cc:** Allen, Samie Niver; Silverman, Phyllis M.

**Subject:** CTD issues

Hi Donna,

It appears from your response to deficiency 7.a. that rheumatologic physical exam findings (i.e. shown Table 11.4 in vol 6) are not included in the symptom categories (i.e. shown in Table 11.2 in vol 6). Could you confirm whether the symptom categories include the rheumatologic physical exam findings?

If not, then could you incorporate the rheumatologic physical exam findings into the symptom categories and re-do the following:

1. All tables summarizing the symptom categories (e.g. Tables 11.2, 11.6 were the ones I could easily find).
2. All statistical analyses/comparisons involving symptom categories (i.e. Table 11.10).
3. Compare the rheumatologic physical exam findings between the SPS and Core Gel (i.e. 11.11).
4. Include the rheumatologic physical exam findings into the combined fatigue, combined pain, and combined fibro (as requested in deficiency 7.b.) and compare this to SPS.
5. Include the rheumatologic physical exam findings into the symptom categories and perform the GEE analysis for age.

If you need help in determining which rheumatologic physical exam finding goes with which symptom category, I can help you with this

Thanks!  
Sahar

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 11.2

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYSTEM  
AUGMENTATION PATIENTS

Sign/System Category	0-12 months (a)	>12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)
Total with at Least One New Sign/System Category	22 ( 4.0)	27 ( 4.9)	17 ( 3.1)	53 ( 9.6)
Skin and Appendages	2 ( 0.4)	4 ( 0.7)	4 ( 0.7)	10 ( 1.8)
Muscle	6 ( 1.1)	8 ( 1.5)	5 ( 0.9)	19 ( 3.4)
Joint	5 ( 0.9)	9 ( 1.6)	3 ( 0.5)	17 ( 3.1)
CNS	7 ( 1.3)	8 ( 1.5)	5 ( 0.9)	20 ( 3.6)
Gastrointestinal	1 ( 0.2)	2 ( 0.4)	1 ( 0.2)	4 ( 0.7)
Body as a Whole	5 ( 0.9)	10 ( 1.8)	4 ( 0.7)	19 ( 3.4)
Metabolic and Nutritional	0 ( 0)	1 ( 0.2)	1 ( 0.2)	2 ( 0.4)
Hearing and Vestibular	1 ( 0.2)	5 ( 0.9)	1 ( 0.2)	7 ( 1.3)
Respiratory	0 ( 0)	2 ( 0.4)	0 ( 0)	2 ( 0.4)
Platelet, Bleeding, Clotting Disorder	1 ( 0.2)	0 ( 0)	1 ( 0.2)	2 ( 0.4)
Cardiovascular	1 ( 0.2)	0 ( 0)	0 ( 0)	1 ( 0.2)
Vision	2 ( 0.4)	3 ( 0.5)	0 ( 0)	5 ( 0.9)

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Table 11.2

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM OR PHYSICAL EXAMINATION FINDINGS BY STGN/SYSTEM  
RECONSTRUCTION PATIENTS

Sign/System Category	0-12 months (a)	>12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)
Total with at Least One New Sign/System Category	21 ( 8.4)	21 ( 8.4)	6 ( 2.4)	44 (17.5)
Skin and Appendages	1 ( 0.4)	0 ( 0)	1 ( 0.4)	2 ( 0.8)
Muscle	6 ( 2.4)	7 ( 2.8)	2 ( 0.8)	15 ( 6.0)
Joint	10 ( 4.0)	8 ( 3.2)	1 ( 0.4)	19 ( 7.6)
CNS	1 ( 0.4)	2 ( 0.8)	1 ( 0.4)	4 ( 1.6)
Gastrointestinal	0 ( 0)	0 ( 0)	1 ( 0.4)	1 ( 0.4)
Body as a Whole	7 ( 2.8)	10 ( 4.0)	2 ( 0.8)	19 ( 7.6)
Metabolic and Nutritional	1 ( 0.4)	0 ( 0)	0 ( 0)	1 ( 0.4)
Hearing and Vestibular	0 ( 0)	1 ( 0.4)	0 ( 0)	1 ( 0.4)
Platelet, Bleeding, Clotting Disorder	0 ( 0)	1 ( 0.4)	0 ( 0)	1 ( 0.4)
Vision	1 ( 0.4)	1 ( 0.4)	0 ( 0)	2 ( 0.8)

(a) Includes only rheumatologic signs/symptoms that had an onset date during the time period of interest.

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 11.2

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYSTEM  
REVISION PATIENTS

Sign/System Category	0-12 months (a)	>12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)
Total with at Least One New Sign/System Category	19 ( 9.3)	18 ( 8.8)	10 ( 4.9)	39 (19.0)
Skin and Appendages	4 ( 2.0)	2 ( 1.0)	3 ( 1.5)	9 ( 4.4)
Muscle	5 ( 2.4)	7 ( 3.4)	3 ( 1.5)	15 ( 7.3)
Joint	7 ( 3.4)	9 ( 4.4)	2 ( 1.0)	18 ( 8.8)
CNS	5 ( 2.4)	8 ( 3.9)	1 ( 0.5)	14 ( 6.8)
Gastrointestinal	2 ( 1.0)	3 ( 1.5)	0 ( 0)	5 ( 2.4)
Body as a Whole	12 ( 5.9)	11 ( 5.4)	1 ( 0.5)	24 (11.7)
Metabolic and Nutritional	1 ( 0.5)	2 ( 1.0)	0 ( 0)	3 ( 1.5)
Hearing and Vestibular	3 ( 1.5)	1 ( 0.5)	1 ( 0.5)	5 ( 2.4)
Respiratory	0 ( 0)	1 ( 0.5)	0 ( 0)	1 ( 0.5)
Platelet, Bleeding, Clotting Disorder	1 ( 0.5)	2 ( 1.0)	1 ( 0.5)	4 ( 2.0)
Vision	0 ( 0)	2 ( 1.0)	0 ( 0)	2 ( 1.0)

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Table 11.2

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYSTEM  
OVERALL PATIENTS

Sign/System Category	0-12 months (a)	>12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)
Total with at Least One New Sign/System Category	62 ( 6.2)	66 ( 6.6)	33 ( 3.3)	136 (13.5)
Skin and Appendages	7 ( 0.7)	6 ( 0.6)	8 ( 0.8)	21 ( 2.1)
Muscle	17 ( 1.7)	22 ( 2.2)	10 ( 1.0)	49 ( 4.9)
Joint	22 ( 2.2)	26 ( 2.6)	6 ( 0.6)	54 ( 5.4)
CNS	13 ( 1.3)	18 ( 1.8)	7 ( 0.7)	38 ( 3.8)
Gastrointestinal	3 ( 0.3)	5 ( 0.5)	2 ( 0.2)	10 ( 1.0)
Body as a Whole	24 ( 2.4)	31 ( 3.1)	7 ( 0.7)	62 ( 6.2)
Metabolic and Nutritional	2 ( 0.2)	3 ( 0.3)	1 ( 0.1)	6 ( 0.6)
Hearing and Vestibular	4 ( 0.4)	7 ( 0.7)	2 ( 0.2)	13 ( 1.3)
Respiratory	0 ( 0)	3 ( 0.3)	0 ( 0)	3 ( 0.3)
Platelet, Bleeding, Clotting Disorder	2 ( 0.2)	3 ( 0.3)	2 ( 0.2)	7 ( 0.7)
Cardiovascular	1 ( 0.1)	0 ( 0)	0 ( 0)	1 ( 0.1)
Vision	3 ( 0.3)	6 ( 0.6)	0 ( 0)	9 ( 0.9)

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
AUGMENTATION PATIENTS

Sign/Symptom	0-12 months (a)	>12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)
Total with at Least One New Sign/Symptom	22 ( 4.0)	27 ( 4.9)	18 ( 3.3)	53 ( 9.6)
LOSS OF WEIGHT WITHOUT DIETING	0 ( 0)	1 ( 0.2)	1 ( 0.2)	2 ( 0.4)
FATIGUE	1 ( 0.2)	6 ( 1.1)	2 ( 0.4)	9 ( 1.6)
INSOMNIA	2 ( 0.4)	5 ( 0.9)	1 ( 0.2)	8 ( 1.5)
WEAKNESS	2 ( 0.4)	2 ( 0.4)	0 ( 0)	4 ( 0.7)
EXHAUSTION	1 ( 0.2)	3 ( 0.5)	1 ( 0.2)	5 ( 0.9)
JOINT SWELLING	3 ( 0.5)	3 ( 0.5)	1 ( 0.2)	7 ( 1.3)
HEEL PAIN	1 ( 0.2)	2 ( 0.4)	2 ( 0.4)	5 ( 0.9)
FREQUENT MUSCLE CRAMPS	1 ( 0.2)	3 ( 0.5)	1 ( 0.2)	5 ( 0.9)
NUMBNESS OF FEET	1 ( 0.2)	3 ( 0.5)	1 ( 0.2)	5 ( 0.9)
RINGING IN EARS	1 ( 0.2)	5 ( 0.9)	1 ( 0.2)	7 ( 1.3)
PAIN/GRITTIENESS IN EYES	2 ( 0.4)	1 ( 0.2)	0 ( 0)	3 ( 0.5)
DRYNESS OF EYES/NOSE	0 ( 0)	1 ( 0.2)	0 ( 0)	1 ( 0.2)
NECK PAIN/STIFFNESS	3 ( 0.5)	3 ( 0.5)	3 ( 0.5)	9 ( 1.6)
HEART MURMURS	1 ( 0.2)	0 ( 0)	0 ( 0)	1 ( 0.2)
LOSS OF APPETITE	0 ( 0)	1 ( 0.2)	0 ( 0)	1 ( 0.2)
NIGHT SWEATS	2 ( 0.4)	3 ( 0.5)	2 ( 0.4)	7 ( 1.3)
GENERALIZED ACHING	0 ( 0)	4 ( 0.7)	1 ( 0.2)	5 ( 0.9)
JOINT PAIN	2 ( 0.4)	8 ( 1.5)	3 ( 0.5)	13 ( 2.4)
FREQUENT MUSCLE PAIN	0 ( 0)	3 ( 0.5)	0 ( 0)	3 ( 0.5)
NUMBNESS OF HANDS	5 ( 0.9)	5 ( 0.9)	3 ( 0.5)	13 ( 2.4)
REDNESS OF EYES	0 ( 0)	2 ( 0.4)	1 ( 0.2)	3 ( 0.5)
DRYNESS OF MOUTH	0 ( 0)	1 ( 0.2)	0 ( 0)	1 ( 0.2)
BACK PAIN/STIFFNESS	2 ( 0.4)	4 ( 0.7)	0 ( 0)	6 ( 1.1)
SEVERE CHEST PAINS	1 ( 0.2)	1 ( 0.2)	0 ( 0)	2 ( 0.4)

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(a) Includes only rheumatologic signs/symptoms that had an onset date during the time period of interest.

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Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
AUGMENTATION PATIENTS

Sign/Symptom	0-12 months (a)	>12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)
CHRONIC COUGH	0 ( 0)	2 ( 0.4)	0 ( 0)	2 ( 0.4)
FREQUENT, SEVERE DIARRHEA/CONSTIPATION	1 ( 0.2)	1 ( 0.2)	1 ( 0.2)	3 ( 0.5)
SEVERE RASHES	1 ( 0.2)	2 ( 0.4)	0 ( 0)	3 ( 0.5)
SEVERE DRYNESS OF SKIN	1 ( 0.2)	0 ( 0)	2 ( 0.4)	3 ( 0.5)
TENDER LUMPS/BUMPS	0 ( 0)	1 ( 0.2)	0 ( 0)	1 ( 0.2)
FREQUENT HIVES	0 ( 0)	1 ( 0.2)	0 ( 0)	1 ( 0.2)
UNUSUAL HAIR LOSS	0 ( 0)	1 ( 0.2)	2 ( 0.4)	3 ( 0.5)
SEVERE BRUISING WITH LITTLE OR NO INJURY	1 ( 0.2)	0 ( 0)	1 ( 0.2)	2 ( 0.4)

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Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
RECONSTRUCTION PATIENTS

Sign/Symptom	0-12 months (a)	>12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)
Total with at Least One New Sign/Symptom	21 ( 8.4)	22 ( 8.8)	6 ( 2.4)	44 (17.5)
LOSS OF WEIGHT WITHOUT DIETING	1 ( 0.4)	0 ( 0)	0 ( 0)	1 ( 0.4)
FATIGUE	2 ( 0.8)	4 ( 1.6)	1 ( 0.4)	7 ( 2.8)
INSOMNIA	1 ( 0.4)	2 ( 0.8)	1 ( 0.4)	4 ( 1.6)
WEAKNESS	1 ( 0.4)	2 ( 0.8)	1 ( 0.4)	4 ( 1.6)
EXHAUSTION	0 ( 0)	2 ( 0.8)	0 ( 0)	2 ( 0.8)
JOINT SWELLING	4 ( 1.6)	6 ( 2.4)	0 ( 0)	10 ( 4.0)
HEEL PAIN	0 ( 0)	1 ( 0.4)	1 ( 0.4)	2 ( 0.8)
FREQUENT MUSCLE CRAMPS	3 ( 1.2)	5 ( 2.0)	0 ( 0)	8 ( 3.2)
RINGING IN EARS	0 ( 0)	1 ( 0.4)	0 ( 0)	1 ( 0.4)
PAIN/GRITTIENESS IN EYES	1 ( 0.4)	1 ( 0.4)	0 ( 0)	2 ( 0.8)
DRYNESS OF EYES/NOSE	1 ( 0.4)	1 ( 0.4)	0 ( 0)	2 ( 0.8)
NECK PAIN/STIFFNESS	0 ( 0)	2 ( 0.8)	2 ( 0.8)	4 ( 1.6)
NIGHT SWEATS	2 ( 0.8)	2 ( 0.8)	1 ( 0.4)	5 ( 2.0)
GENERALIZED ACHING	1 ( 0.4)	2 ( 0.8)	0 ( 0)	3 ( 1.2)
LOSS OF HEIGHT	2 ( 0.8)	2 ( 0.8)	0 ( 0)	4 ( 1.6)
JOINT PAIN	9 ( 3.6)	7 ( 2.8)	1 ( 0.4)	17 ( 6.8)
FREQUENT MUSCLE PAIN	2 ( 0.8)	2 ( 0.8)	0 ( 0)	4 ( 1.6)
JAW PAIN	0 ( 0)	0 ( 0)	1 ( 0.4)	1 ( 0.4)
BACK PAIN/STIFFNESS	2 ( 0.8)	1 ( 0.4)	0 ( 0)	3 ( 1.2)
FREQUENT, SEVERE DIARRHEA/CONSTIPATION	0 ( 0)	0 ( 0)	1 ( 0.4)	1 ( 0.4)
TENDER LUMPS/BUMPS	0 ( 0)	1 ( 0.4)	0 ( 0)	1 ( 0.4)
UNUSUAL HAIR LOSS	1 ( 0.4)	0 ( 0)	1 ( 0.4)	2 ( 0.8)
TENDERNESS OF SCALP	1 ( 0.4)	0 ( 0)	0 ( 0)	1 ( 0.4)
SEVERE BRUISING WITH LITTLE OR NO INJURY	0 ( 0)	1 ( 0.4)	0 ( 0)	1 ( 0.4)

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Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
REVISION PATIENTS

Sign/Symptom	0-12 months (a)	>12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)
Total with at Least One New Sign/Symptom	19 ( 9.3)	18 ( 8.8)	10 ( 4.9)	39 (19.0)
LOSS OF WEIGHT WITHOUT DIETING	1 ( 0.5)	2 ( 1.0)	0 ( 0)	3 ( 1.5)
FATIGUE	5 ( 2.4)	4 ( 2.0)	2 ( 1.0)	11 ( 5.4)
INSOMNIA	2 ( 1.0)	3 ( 1.5)	0 ( 0)	5 ( 2.4)
WEAKNESS	2 ( 1.0)	3 ( 1.5)	1 ( 0.5)	6 ( 2.9)
EXHAUSTION	1 ( 0.5)	4 ( 2.0)	1 ( 0.5)	6 ( 2.9)
JOINT SWELLING	1 ( 0.5)	5 ( 2.4)	3 ( 1.5)	9 ( 4.4)
HEEL PAIN	2 ( 1.0)	0 ( 0)	0 ( 0)	2 ( 1.0)
FREQUENT MUSCLE CRAMPS	1 ( 0.5)	3 ( 1.5)	1 ( 0.5)	5 ( 2.4)
NUMBNESS OF FEET	2 ( 1.0)	1 ( 0.5)	1 ( 0.5)	4 ( 2.0)
RINGING IN EARS	3 ( 1.5)	1 ( 0.5)	1 ( 0.5)	5 ( 2.4)
DRYNESS OF EYES/NOSE	1 ( 0.5)	1 ( 0.5)	0 ( 0)	2 ( 1.0)
PAIN ON SWALLOWING OR CHEWING	0 ( 0)	2 ( 1.0)	0 ( 0)	2 ( 1.0)
NECK PAIN/STIFFNESS	3 ( 1.5)	1 ( 0.5)	0 ( 0)	4 ( 2.0)
PAIN ON BREATHING	0 ( 0)	1 ( 0.5)	0 ( 0)	1 ( 0.5)
LOSS OF APPETITE	0 ( 0)	2 ( 1.0)	0 ( 0)	2 ( 1.0)
NIGHT SWEATS	3 ( 1.5)	1 ( 0.5)	0 ( 0)	4 ( 2.0)
GENERALIZED ACHING	2 ( 1.0)	4 ( 2.0)	1 ( 0.5)	7 ( 3.4)
LOSS OF HEIGHT	0 ( 0)	1 ( 0.5)	0 ( 0)	1 ( 0.5)
JOINT PAIN	7 ( 3.4)	7 ( 3.4)	0 ( 0)	14 ( 6.8)
FREQUENT MUSCLE PAIN	2 ( 1.0)	1 ( 0.5)	0 ( 0)	3 ( 1.5)
NUMBNESS OF HANDS	1 ( 0.5)	6 ( 2.9)	1 ( 0.5)	8 ( 3.9)
JAW PAIN	1 ( 0.5)	0 ( 0)	0 ( 0)	1 ( 0.5)
REDNESS OF EYES	0 ( 0)	2 ( 1.0)	0 ( 0)	2 ( 1.0)
DRYNESS OF MOUTH	1 ( 0.5)	1 ( 0.5)	0 ( 0)	2 ( 1.0)

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(a) Includes only rheumatologic signs/symptoms that had an onset date during the time period of interest.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
REVISION PATIENTS

Sign/Symptom	0-12 months (a)	>12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)
BACK PAIN/STIFFNESS	2 ( 1.0)	4 ( 2.0)	2 ( 1.0)	8 ( 3.9)
DIFFICULTY SWALLOWING	0 ( 0)	2 ( 1.0)	0 ( 0)	2 ( 1.0)
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	2 ( 1.0)	2 ( 1.0)	0 ( 0)	4 ( 2.0)
SEVERE DRYNESS OF SKIN	1 ( 0.5)	2 ( 1.0)	2 ( 1.0)	5 ( 2.4)
TENDER LUMPS/BUMPS	2 ( 1.0)	2 ( 1.0)	1 ( 0.5)	5 ( 2.4)
EXCESSIVE SENSITIVITY TO SUN	1 ( 0.5)	0 ( 0)	0 ( 0)	1 ( 0.5)
COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE	2 ( 1.0)	0 ( 0)	0 ( 0)	2 ( 1.0)
FREQUENT HIVES	1 ( 0.5)	0 ( 0)	0 ( 0)	1 ( 0.5)
UNUSUAL HAIR LOSS	2 ( 1.0)	1 ( 0.5)	1 ( 0.5)	4 ( 2.0)
TENDERNESS OF SCALP	1 ( 0.5)	0 ( 0)	0 ( 0)	1 ( 0.5)
SEVERE BRUISING WITH LITTLE OR NO INJURY	1 ( 0.5)	2 ( 1.0)	1 ( 0.5)	4 ( 2.0)

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Table 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
OVERALL PATIENTS

Sign/Symptom	0-12 months (a)	>12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)
Total with at Least One New Sign/Symptom	62 ( 6.2)	67 ( 6.7)	34 ( 3.4)	136 (13.5)
LOSS OF WEIGHT WITHOUT DIETING	2 ( 0.2)	3 ( 0.3)	1 ( 0.1)	6 ( 0.6)
FATIGUE	8 ( 0.8)	14 ( 1.4)	5 ( 0.5)	27 ( 2.7)
INSOMNIA	5 ( 0.5)	10 ( 1.0)	2 ( 0.2)	17 ( 1.7)
WEAKNESS	5 ( 0.5)	7 ( 0.7)	2 ( 0.2)	14 ( 1.4)
EXHAUSTION	2 ( 0.2)	9 ( 0.9)	2 ( 0.2)	13 ( 1.3)
JOINT SWELLING	8 ( 0.8)	14 ( 1.4)	4 ( 0.4)	26 ( 2.6)
HEEL PAIN	3 ( 0.3)	3 ( 0.3)	3 ( 0.3)	9 ( 0.9)
FREQUENT MUSCLE CRAMPS	5 ( 0.5)	11 ( 1.1)	2 ( 0.2)	18 ( 1.8)
NUMBNESS OF FEET	3 ( 0.3)	4 ( 0.4)	2 ( 0.2)	9 ( 0.9)
RINGING IN EARS	4 ( 0.4)	7 ( 0.7)	2 ( 0.2)	13 ( 1.3)
PAIN/GRITTIENESS IN EYES	3 ( 0.3)	2 ( 0.2)	0 ( 0)	5 ( 0.5)
DRYNESS OF EYES/NOSE	2 ( 0.2)	3 ( 0.3)	0 ( 0)	5 ( 0.5)
PAIN ON SWALLOWING OR CHEWING	0 ( 0)	2 ( 0.2)	0 ( 0)	2 ( 0.2)
NECK PAIN/STIFFNESS	6 ( 0.6)	6 ( 0.6)	5 ( 0.5)	17 ( 1.7)
PAIN ON BREATHING	0 ( 0)	1 ( 0.1)	0 ( 0)	1 ( 0.1)
HEART MURMURS	1 ( 0.1)	0 ( 0)	0 ( 0)	1 ( 0.1)
LOSS OF APPETITE	0 ( 0)	3 ( 0.3)	0 ( 0)	3 ( 0.3)
NIGHT SWEATS	7 ( 0.7)	6 ( 0.6)	3 ( 0.3)	16 ( 1.6)
GENERALIZED ACHING	3 ( 0.3)	10 ( 1.0)	2 ( 0.2)	15 ( 1.5)
LOSS OF HEIGHT	2 ( 0.2)	3 ( 0.3)	0 ( 0)	5 ( 0.5)
JOINT PAIN	18 ( 1.8)	22 ( 2.2)	4 ( 0.4)	44 ( 4.4)
FREQUENT MUSCLE PAIN	4 ( 0.4)	6 ( 0.6)	0 ( 0)	10 ( 1.0)
NUMBNESS OF HANDS	6 ( 0.6)	11 ( 1.1)	4 ( 0.4)	21 ( 2.1)
JAW PAIN	1 ( 0.1)	0 ( 0)	1 ( 0.1)	2 ( 0.2)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_3.SAS

Creation Date, Time: 17DEC04 10:06

(a) Includes only rheumatologic signs/symptoms that had an onset date during the time period of interest.

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 11.3

INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOM OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
OVERALL PATIENTS

Sign/Symptom	0-12 months (a)	>12-24 months (a)	>24-36 months (a)	0-36 months (a)
	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)	Number of Patients n(%)
REDNESS OF EYES	0 ( 0)	4 ( 0.4)	1 ( 0.1)	5 ( 0.5)
DRYNESS OF MOUTH	1 ( 0.1)	2 ( 0.2)	0 ( 0)	3 ( 0.3)
BACK PAIN/STIFFNESS	6 ( 0.6)	9 ( 0.9)	2 ( 0.2)	17 ( 1.7)
SEVERE CHEST PAINS	1 ( 0.1)	1 ( 0.1)	0 ( 0)	2 ( 0.2)
CHRONIC COUGH	0 ( 0)	2 ( 0.2)	0 ( 0)	2 ( 0.2)
DIFFICULTY SWALLOWING	0 ( 0)	2 ( 0.2)	0 ( 0)	2 ( 0.2)
FREQUENT, SEVERE DIARRHEA/CONSTIPATION	3 ( 0.3)	3 ( 0.3)	2 ( 0.2)	8 ( 0.8)
SEVERE RASHES	1 ( 0.1)	2 ( 0.2)	0 ( 0)	3 ( 0.3)
SEVERE DRYNESS OF SKIN	2 ( 0.2)	2 ( 0.2)	4 ( 0.4)	8 ( 0.8)
TENDER LUMPS/BUMPS	2 ( 0.2)	4 ( 0.4)	1 ( 0.1)	7 ( 0.7)
EXCESSIVE SENSITIVITY TO SUN	1 ( 0.1)	0 ( 0)	0 ( 0)	1 ( 0.1)
COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE	2 ( 0.2)	0 ( 0)	0 ( 0)	2 ( 0.2)
FREQUENT HIVES	1 ( 0.1)	1 ( 0.1)	0 ( 0)	2 ( 0.2)
UNUSUAL HAIR LOSS	3 ( 0.3)	2 ( 0.2)	4 ( 0.4)	9 ( 0.9)
TENDERNESS OF SCALP	2 ( 0.2)	0 ( 0)	0 ( 0)	2 ( 0.2)
SEVERE BRUISING WITH LITTLE OR NO INJURY	2 ( 0.2)	3 ( 0.3)	2 ( 0.2)	7 ( 0.7)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_3.SAS

Creation Date, Time: 17DEC04 10:06

(a) Includes only rheumatologic signs/symptoms that had an onset date during the time period of interest.

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 11.6

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYSTEM CATEGORY  
AUGMENTATION PATIENTS

Sign/System Category	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/System Category	Estimated Proportion with Sign/System Category (b)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (b)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (b)
Skin and Appendages	2	0.0037	6	0.0113	10	0.0213
Muscle	6	0.0110	14	0.0263	19	0.0392
Joint	5	0.0092	14	0.0261	17	0.0336
CNS	7	0.0128	15	0.0279	20	0.0407
Gastrointestinal	1	0.0018	3	0.0056	4	0.0081
Body as a Whole	5	0.0092	15	0.0280	19	0.0375
Metabolic and Nutritional	0	0.0000	1	0.0019	2	0.0044
Hearing and Vestibular	1	0.0018	6	0.0115	7	0.0140
Respiratory	0	0.0000	2	0.0038	2	0.0038
Platelet, Bleeding, Clotting Disorder	1	0.0018	1	0.0018	2	0.0043
Cardiovascular	1	0.0018	1	0.0018	1	0.0018
Vision	2	0.0037	5	0.0093	5	0.0093
Any of the Above	22	0.0402	46	0.0858	53	0.1030
Total Patients Assessed	551		551		551	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_6.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:21

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 11.6

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYSTEM CATEGORY  
RECONSTRUCTION PATIENTS

Sign/System Category	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/System Category	Estimated Proportion with Sign/System Category (b)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (b)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (b)
Skin and Appendages	1	0.0040	1	0.0040	2	0.0124
Muscle	6	0.0249	13	0.0564	15	0.0763
Joint	10	0.0417	18	0.0780	19	0.0857
CNS	1	0.0043	3	0.0131	4	0.0214
Gastrointestinal	0	0.0000	0	0.0000	1	0.0084
Body as a Whole	7	0.0290	17	0.0799	19	0.0962
Metabolic and Nutritional	1	0.0043	1	0.0043	1	0.0043
Hearing and Vestibular	0	0.0000	1	0.0046	1	0.0046
Respiratory	0	0.0000	0	0.0000	0	0.0000
Platelet, Bleeding, Clotting Disorder	0	0.0000	1	0.0047	1	0.0047
Cardiovascular	0	0.0000	0	0.0000	0	0.0000
Vision	1	0.0040	2	0.0084	2	0.0084
Any of the Above	21	0.0866	40	0.1779	44	0.2149
Total Patients Assessed	251		251		251	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_6.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:21

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 11.6

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYSTEM CATEGORY  
REVISION PATIENTS

Sign/System Category	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/System Category	Estimated Proportion with Sign/System Category (b)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (b)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (b)
Skin and Appendages	4	0.0198	6	0.0304	9	0.0561
Muscle	5	0.0248	12	0.0619	15	0.0837
Joint	7	0.0346	16	0.0830	18	0.0977
CNS	5	0.0248	13	0.0668	14	0.0732
Gastrointestinal	2	0.0099	5	0.0257	5	0.0257
Body as a Whole	12	0.0596	23	0.1177	24	0.1249
Metabolic and Nutritional	1	0.0050	3	0.0156	3	0.0156
Hearing and Vestibular	3	0.0148	4	0.0201	5	0.0267
Respiratory	0	0.0000	1	0.0053	1	0.0053
Platelet, Bleeding, Clotting Disorder	1	0.0050	3	0.0155	4	0.0220
Cardiovascular	0	0.0000	0	0.0000	0	0.0000
Vision	0	0.0000	2	0.0107	2	0.0107
Any of the Above	19	0.0941	34	0.1737	39	0.2128
Total Patients Assessed	205		205		205	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_6.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time. 17DEC04 10:21

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 11.6

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYSTEM CATEGORY  
OVERALL PATIENTS

Sign/System Category	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/System Category	Estimated Proportion with Sign/System Category (b)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (b)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (b)
Skin and Appendages	7	0.0071	13	0.0136	21	0.0265
Muscle	17	0.0172	39	0.0408	49	0.0566
Joint	22	0.0223	48	0.0502	54	0.0593
CNS	13	0.0132	31	0.0323	38	0.0432
Gastrointestinal	3	0.0030	8	0.0083	10	0.0114
Body as a Whole	24	0.0243	55	0.0578	62	0.0680
Metabolic and Nutritional	2	0.0021	5	0.0053	6	0.0068
Hearing and Vestibular	4	0.0040	11	0.0117	13	0.0147
Respiratory	0	0.0000	3	0.0032	3	0.0032
Platelet, Bleeding, Clotting Disorder	2	0.0020	5	0.0052	7	0.0082
Cardiovascular	1	0.0010	1	0.0010	1	0.0010
Vision	3	0.0030	9	0.0094	9	0.0094
Any of the Above	62	0.0625	120	0.1251	136	0.1500
Total Patients Assessed	1007		1007		1007	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_6.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:21

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 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
AUGMENTATION PATIENTS

Sign/Symptom	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)
LOSS OF WEIGHT WITHOUT DIETING	0	0.0000	1	0.0019	2	0.0044
FATIGUE	1	0.0018	7	0.0132	9	0.0177
INSOMNIA	2	0.0037	7	0.0131	8	0.0153
WEAKNESS	2	0.0037	4	0.0075	4	0.0075
EXHAUSTION	1	0.0018	4	0.0075	5	0.0100
JOINT SWELLING	3	0.0055	6	0.0111	7	0.0141
HEEL PAIN	1	0.0018	3	0.0056	5	0.0108
FREQUENT MUSCLE CRAMPS	1	0.0018	4	0.0075	5	0.0100
NUMBNESS OF FEET	1	0.0018	4	0.0075	5	0.0100
RINGING IN EARS	1	0.0018	6	0.0115	7	0.0140
PAIN/GRITTIENESS IN EYES	2	0.0037	3	0.0055	3	0.0055
DRYNESS OF EYES/NOSE	0	0.0000	1	0.0019	1	0.0019
PAIN ON SWALLOWING OR CHEWING	0	0.0000	0	0.0000	0	0.0000
NECK PAIN/STIFFNESS	3	0.0055	6	0.0112	9	0.0188
PAIN ON BREATHING	0	0.0000	0	0.0000	0	0.0000
HEART MURMURS	1	0.0018	1	0.0018	1	0.0018
LOSS OF APPETITE	0	0.0000	1	0.0019	1	0.0019
PERSISTENT FEVER	0	0.0000	0	0.0000	0	0.0000
NIGHT SWEATS	2	0.0036	5	0.0093	7	0.0143
GENERALIZED ACHING	0	0.0000	4	0.0075	5	0.0105
LOSS OF HEIGHT	0	0.0000	0	0.0000	0	0.0000

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_7.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:08

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 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
AUGMENTATION PATIENTS

Sign/Symptom	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)
JOINT PAIN	2	0.0037	10	0.0187	13	0.0262
FREQUENT MUSCLE PAIN	0	0.0000	3	0.0057	3	0.0057
NUMBNESS OF HANDS	5	0.0091	10	0.0185	13	0.0266
JAW PAIN	0	0.0000	0	0.0000	0	0.0000
OPEN SORES	0	0.0000	0	0.0000	0	0.0000
REDNESS OF EYES	0	0.0000	2	0.0038	3	0.0063
DRYNESS OF MOUTH	0	0.0000	1	0.0019	1	0.0019
BACK PAIN/STIFFNESS	2	0.0036	6	0.0114	6	0.0114
SEVERE CHEST PAINS	1	0.0018	2	0.0037	2	0.0037
CHRONIC COUGH	0	0.0000	2	0.0038	2	0.0038
DIFFICULTY SWALLOWING	0	0.0000	0	0.0000	0	0.0000
FREQUENT, SEVERE DIARRHEA/CONSTIPATION	1	0.0018	2	0.0037	3	0.0062
SEVERE RASHES	1	0.0018	3	0.0056	3	0.0056
SEVERE DRYNESS OF SKIN	1	0.0018	1	0.0018	3	0.0068
TENDER LUMPS/BUMPS	0	0.0000	1	0.0019	1	0.0019
EXCESSIVE SENSITIVITY TO SUN	0	0.0000	0	0.0000	0	0.0000
COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE	0	0.0000	0	0.0000	0	0.0000
FREQUENT HIVES	0	0.0000	1	0.0020	1	0.0020
TIGHTNESS OF SKIN	0	0.0000	0	0.0000	0	0.0000
UNUSUAL HAIR LOSS	0	0.0000	1	0.0019	3	0.0069

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_7.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:08

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 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
 AUGMENTATION PATIENTS

Sign/Symptom	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)
TENDERNESS OF SCALP	0	0.0000	0	0.0000	0	0.0000
SEVERE BRUISING WITH LITTLE OR NO INJURY	1	0.0018	1	0.0018	2	0.0043
Any of the Above	22	0.0402	46	0.0858	53	0.1030
Total Patients Assessed	551		551		551	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_7.SAS  
 (a) Time from implant surgery to first occurrence of event.  
 (b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:08

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 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
RECONSTRUCTION PATIENTS

Sign/Symptom	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)
LOSS OF WEIGHT WITHOUT DIETING	1	0.0043	1	0.0043	1	0.0043
FATIGUE	2	0.0083	6	0.0286	7	0.0371
INSOMNIA	1	0.0043	3	0.0131	4	0.0214
WEAKNESS	1	0.0042	3	0.0132	4	0.0215
EXHAUSTION	0	0.0000	2	0.0090	2	0.0090
JOINT SWELLING	4	0.0168	10	0.0449	10	0.0449
HEEL PAIN	0	0.0000	1	0.0046	2	0.0130
FREQUENT MUSCLE CRAMPS	3	0.0125	8	0.0351	8	0.0351
NUMBNESS OF FEET	0	0.0000	0	0.0000	0	0.0000
RINGING IN EARS	0	0.0000	1	0.0046	1	0.0046
PAIN/GRITTIENESS IN EYES	1	0.0040	2	0.0084	2	0.0084
DRYNESS OF EYES/NOSE	1	0.0040	2	0.0084	2	0.0084
PAIN ON SWALLOWING OR CHEWING	0	0.0000	0	0.0000	0	0.0000
NECK PAIN/STIFFNESS	0	0.0000	2	0.0090	4	0.0299
PAIN ON BREATHING	0	0.0000	0	0.0000	0	0.0000
HEART MURMURS	0	0.0000	0	0.0000	0	0.0000
LOSS OF APPETITE	0	0.0000	0	0.0000	0	0.0000
PERSISTENT FEVER	0	0.0000	0	0.0000	0	0.0000
NIGHT SWEATS	2	0.0084	4	0.0194	5	0.0277
GENERALIZED ACHING	1	0.0042	3	0.0130	3	0.0130
LOSS OF HEIGHT	2	0.0085	4	0.0175	4	0.0175

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_7.SAS

Creation Date, Time 17DEC04 10:08

(a) Time from implant surgery to first occurrence of event.

(b) Based on Kaplan-Meier Estimates.

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 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
RECONSTRUCTION PATIENTS

Sign/Symptom	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)
JOINT PAIN	9	0.0375	16	0.0721	17	0.0798
FREQUENT MUSCLE PAIN	2	0.0084	4	0.0175	4	0.0175
NUMBNESS OF HANDS	0	0.0000	0	0.0000	0	0.0000
JAW PAIN	0	0.0000	0	0.0000	1	0.0084
OPEN SORES	0	0.0000	0	0.0000	0	0.0000
REDNESS OF EYES	0	0.0000	0	0.0000	0	0.0000
DRYNESS OF MOUTH	0	0.0000	0	0.0000	0	0.0000
BACK PAIN/STIFFNESS	2	0.0083	3	0.0127	3	0.0127
SEVERE CHEST PAINS	0	0.0000	0	0.0000	0	0.0000
CHRONIC COUGH	0	0.0000	0	0.0000	0	0.0000
DIFFICULTY SWALLOWING	0	0.0000	0	0.0000	0	0.0000
FREQUENT, SEVERE DIARRHEA/CONSTIPATION	0	0.0000	0	0.0000	1	0.0084
SEVERE RASHES	0	0.0000	0	0.0000	0	0.0000
SEVERE DRYNESS OF SKIN	0	0.0000	0	0.0000	0	0.0000
TENDER LUMPS/BUMPS	0	0.0000	1	0.0068	1	0.0068
EXCESSIVE SENSITIVITY TO SUN	0	0.0000	0	0.0000	0	0.0000
COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE	0	0.0000	0	0.0000	0	0.0000
FREQUENT HIVES	0	0.0000	0	0.0000	0	0.0000
TIGHTNESS OF SKIN	0	0.0000	0	0.0000	0	0.0000
UNUSUAL HAIR LOSS	1	0.0040	1	0.0040	2	0.0124

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_7.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:08

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 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
RECONSTRUCTION PATIENTS

Sign/Symptom	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)
TENDERNESS OF SCALP	1	0.0043	1	0.0043	1	0.0043
SEVERE BRUISING WITH LITTLE OR NO INJURY	0	0.0000	1	0.0047	1	0.0047
Any of the Above	21	0.0866	40	0.1779	44	0.2149
Total Patients Assessed	251		251		251	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_7.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:08

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 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
REVISION PATIENTS

Sign/Symptom	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)
LOSS OF WEIGHT WITHOUT DIETING	1	0.0050	3	0.0156	3	0.0156
FATIGUE	5	0.0249	9	0.0460	11	0.0595
INSOMNIA	2	0.0099	5	0.0258	5	0.0258
WEAKNESS	2	0.0099	5	0.0259	6	0.0324
EXHAUSTION	1	0.0050	5	0.0262	6	0.0327
JOINT SWELLING	1	0.0049	6	0.0312	9	0.0522
HEEL PAIN	2	0.0099	2	0.0099	2	0.0099
FREQUENT MUSCLE CRAMPS	1	0.0050	4	0.0206	5	0.0278
NUMBNESS OF FEET	2	0.0099	3	0.0160	4	0.0225
RINGING IN EARS	3	0.0148	4	0.0201	5	0.0267
PAIN/GRITTIENESS IN EYES	0	0.0000	0	0.0000	0	0.0000
DRYNESS OF EYES/NOSE	1	0.0050	2	0.0102	2	0.0102
PAIN ON SWALLOWING OR CHEWING	0	0.0000	2	0.0107	2	0.0107
NECK PAIN/STIFFNESS	3	0.0149	4	0.0202	4	0.0202
PAIN ON BREATHING	0	0.0000	1	0.0053	1	0.0053
HEART MURMURS	0	0.0000	0	0.0000	0	0.0000
LOSS OF APPETITE	0	0.0000	2	0.0106	2	0.0106
PERSISTENT FEVER	0	0.0000	0	0.0000	0	0.0000
NIGHT SWEATS	3	0.0148	4	0.0200	4	0.0200
GENERALIZED ACHING	2	0.0099	6	0.0321	7	0.0387
LOSS OF HEIGHT	0	0.0000	1	0.0053	1	0.0053

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_7.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:08

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 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
REVISION PATIENTS

Sign/Symptom	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)
JOINT PAIN	7	0.0346	14	0.0731	14	0.0731
FREQUENT MUSCLE PAIN	2	0.0099	3	0.0152	3	0.0152
NUMBNESS OF HANDS	1	0.0050	7	0.0366	8	0.0431
JAW PAIN	1	0.0050	1	0.0050	1	0.0050
OPEN SORES	0	0.0000	0	0.0000	0	0.0000
REDNESS OF EYES	0	0.0000	2	0.0107	2	0.0107
DRYNESS OF MOUTH	1	0.0050	2	0.0103	2	0.0103
BACK PAIN/STIFFNESS	2	0.0099	6	0.0321	8	0.0469
SEVERE CHEST PAINS	0	0.0000	0	0.0000	0	0.0000
CHRONIC COUGH	0	0.0000	0	0.0000	0	0.0000
DIFFICULTY SWALLOWING	0	0.0000	2	0.0107	2	0.0107
FREQUENT, SEVERE DIARRHEA/CONSTIPATION	2	0.0099	4	0.0204	4	0.0204
SEVERE RASHES	0	0.0000	0	0.0000	0	0.0000
SEVERE DRYNESS OF SKIN	1	0.0050	3	0.0156	5	0.0328
TENDER LUMPS/BUMPS	2	0.0099	4	0.0203	5	0.0269
EXCESSIVE SENSITIVITY TO SUN	1	0.0050	1	0.0050	1	0.0050
COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE	2	0.0099	2	0.0099	2	0.0099
FREQUENT HIVES	1	0.0049	1	0.0049	1	0.0049
TIGHTNESS OF SKIN	0	0.0000	0	0.0000	0	0.0000
UNUSUAL HAIR LOSS	2	0.0100	3	0.0152	4	0.0237

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_7.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:08

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 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
REVISION PATIENTS

Sign/Symptom	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)
TENDERNESS OF SCALP	1	0.0049	1	0.0049	1	0.0049
SEVERE BRUISING WITH LITTLE OR NO INJURY	1	0.0050	3	0.0155	4	0.0220
Any of the Above	19	0.0941	34	0.1737	39	0.2128
Total Patients Assessed	205		205		205	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_7.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:08

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 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
OVERALL PATIENTS

Sign/Symptom	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)
LOSS OF WEIGHT WITHOUT DIETING	2	0.0021	5	0.0053	6	0.0068
FATIGUE	8	0.0081	22	0.0232	27	0.0304
INSOMNIA	5	0.0051	15	0.0158	17	0.0186
WEAKNESS	5	0.0051	12	0.0126	14	0.0155
EXHAUSTION	2	0.0020	11	0.0116	13	0.0146
JOINT SWELLING	8	0.0081	22	0.0231	26	0.0295
HEEL PAIN	3	0.0030	6	0.0062	9	0.0109
FREQUENT MUSCLE CRAMPS	5	0.0051	16	0.0167	18	0.0198
NUMBNESS OF FEET	3	0.0030	7	0.0076	9	0.0105
RINGING IN EARS	4	0.0040	11	0.0117	13	0.0147
PAIN/GRITTIENESS IN EYES	3	0.0030	5	0.0051	5	0.0051
DRYNESS OF EYES/NOSE	2	0.0020	5	0.0052	5	0.0052
PAIN ON SWALLOWING OR CHEWING	0	0.0000	2	0.0022	2	0.0022
NECK PAIN/STIFFNESS	6	0.0061	12	0.0125	17	0.0206
PAIN ON BREATHING	0	0.0000	1	0.0011	1	0.0011
HEART MURMURS	1	0.0010	1	0.0010	1	0.0010
LOSS OF APPETITE	0	0.0000	3	0.0032	3	0.0032
PERSISTENT FEVER	0	0.0000	0	0.0000	0	0.0000
NIGHT SWEATS	7	0.0070	13	0.0136	16	0.0181
GENERALIZED ACHING	3	0.0030	13	0.0140	15	0.0174
LOSS OF HEIGHT	2	0.0021	5	0.0052	5	0.0052

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_7.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:08

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 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
OVERALL PATIENTS

Sign/Symptom	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)
JOINT PAIN	18	0.0182	40	0.0423	44	0.0483
FREQUENT MUSCLE PAIN	4	0.0040	10	0.0104	10	0.0104
NUMBNESS OF HANDS	6	0.0060	17	0.0178	21	0.0243
JAW PAIN	1	0.0010	1	0.0010	2	0.0025
OPEN SORES	0	0.0000	0	0.0000	0	0.0000
REDNESS OF EYES	0	0.0000	4	0.0043	5	0.0058
DRYNESS OF MOUTH	1	0.0010	3	0.0032	3	0.0032
BACK PAIN/STIFFNESS	6	0.0060	15	0.0161	17	0.0192
SEVERE CHEST PAINS	1	0.0010	2	0.0021	2	0.0021
CHRONIC COUGH	0	0.0000	2	0.0021	2	0.0021
DIFFICULTY SWALLOWING	0	0.0000	2	0.0022	2	0.0022
FREQUENT, SEVERE DIARRHEA/CONSTIPATION	3	0.0030	6	0.0062	8	0.0092
SEVERE RASHES	1	0.0010	3	0.0032	3	0.0032
SEVERE DRYNESS OF SKIN	2	0.0020	4	0.0042	8	0.0107
TENDER LUMPS/BUMPS	2	0.0020	6	0.0065	7	0.0079
EXCESSIVE SENSITIVITY TO SUN	1	0.0010	1	0.0010	1	0.0010
COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE	2	0.0020	2	0.0020	2	0.0020
FREQUENT HIVES	1	0.0010	2	0.0022	2	0.0022
TIGHTNESS OF SKIN	0	0.0000	0	0.0000	0	0.0000
UNUSUAL HAIR LOSS	3	0.0030	5	0.0052	9	0.0115

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_7.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10.08

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 11.7

CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM  
OVERALL PATIENTS

Sign/Symptom	Time from Implant Surgery (a)					
	12 months		24 months		36 months	
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)
TENDERNESS OF SCALP	2	0.0020	2	0.0020	2	0.0020
SEVERE BRUISING WITH LITTLE OR NO INJURY	2	0.0020	5	0.0052	7	0.0082
Any of the Above	62	0.0625	120	0.1251	136	0.1500
Total Patients Assessed	1007		1007		1007	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_7.SAS  
(a) Time from implant surgery to first occurrence of event.  
(b) Based on Kaplan-Meier Estimates.

Creation Date, Time: 17DEC04 10:08

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 11.10

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYSTEM CATEGORY - FDA Item 7b(1)  
AUGMENTATION PATIENTS

Sign/System Category	36 Months after Implant Surgery (a)				
	SPS		CoreGel (b)		P-value (d)
	Number with Sign/System Category	Estimated Proportion with Sign/System Category (c)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (c)	
Skin and Appendages	61	0.0065	10	0.0213	
Muscle	197	0.0258	19	0.0392	0.1198
Joint	75	0.0050	17	0.0336	0.0000
CNS	101	0.0359	20	0.0407	0.5225
Gastrointestinal	53	0.0142	4	0.0081	0.3452
Body as a Whole	317	0.0124	19	0.0375	0.0000
Metabolic and Nutritional	15	0.0160	2	0.0044	0.0625
Hearing and Vestibular	19	0.0201	7	0.0140	0.4246
Respiratory	7	0.0041	2	0.0038	0.9728
Platelet, Bleeding, Clotting Disorder	14	0.0147	2	0.0043	0.0606
Vascular System					1.0000
Cardiovascular	20	0.0201	1	0.0018	0.0033
Vision	17	0.0042	5	0.0093	0.1528
Any of the Above	329	0.3336	53	0.1030	0.0000
Total Patients Assessed	1264		551		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_10.SAS

Creation Date, Time: 17DEC04 10:24

(a) Time from implant surgery to first occurrence of event.

(b) Excludes data on revision patients.

(c) Based on Kaplan-Meier estimates.

(d) p-value is from log-rank test of estimated proportion among patients in SPS versus CoreGel.

Note: Sign/System categories were reviewed and approved by the FDA for the SPS report.

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 11.10

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYSTEM CATEGORY - FDA Item 7b(1)  
RECONSTRUCTION PATIENTS

Sign/System Category	36 Months after Implant Surgery (a)				P-value (d)
	SPS		CoreGel (b)		
	Number with Sign/System Category	Estimated Proportion with Sign/System Category (c)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (c)	
Skin and Appendages	37	0.0151	2	0.0124	0.9183
Muscle	87	0.0420	15	0.0763	0.0008
Joint	69	0.0179	19	0.0857	0.0000
CNS	51	0.0685	4	0.0214	0.1165
Gastrointestinal	30	0.0294	1	0.0084	0.3387
Body as a Whole	203	0.0309	19	0.0962	0.0000
Metabolic and Nutritional	9	0.0462	1	0.0043	0.1220
Hearing and Vestibular	6	0.0247	1	0.0046	0.1719
Respiratory	7	0.0164	0	0.0000	0.1872
Platelet, Bleeding, Clotting Disorder	7	0.0303	1	0.0047	0.1149
Vascular System					1.0000
Cardiovascular	3	0.0103	0	0.0000	0.1585
Vision	9	0.0079	2	0.0084	0.5755
Any of the Above	138	0.5025	44	0.2149	0.0004
Total Patients Assessed	416		251		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_10.SAS

Creation Date, Time: 17DEC04 10:24

(a) Time from implant surgery to first occurrence of event.

(b) Excludes data on revision patients.

(c) Based on Kaplan-Meier estimates.

(d) p-value is from log-rank test of estimated proportion among patients in SPS versus CoreGel.

Note: Sign/System categories were reviewed and approved by the FDA for the SPS report.

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 11.10

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYSTEM CATEGORY - FDA Item 7b(1)  
OVERALL PATIENTS

Sign/System Category	36 Months after Implant Surgery (a)				P-value (d)
	SPS		CoreGel (b)		
	Number with Sign/System Category	Estimated Proportion with Sign/System Category (c)	Number with Sign/System Category	Estimated Proportion with Sign/System Category (c)	
Skin and Appendages	98	0.0082	12	0.0189	0.0019
Muscle	284	0.0293	34	0.0496	0.0011
Joint	144	0.0076	36	0.0494	0.0000
CNS	152	0.0426	24	0.0355	0.7249
Gastrointestinal	83	0.0174	5	0.0078	0.1874
Body as a Whole	520	0.0160	38	0.0536	0.0000
Metabolic and Nutritional	24	0.0206	3	0.0046	0.0197
Hearing and Vestibular	25	0.0212	8	0.0116	0.1656
Respiratory	14	0.0063	2	0.0027	0.4109
Platelet, Bleeding, Clotting Disorder	21	0.0176	3	0.0045	0.0146
Vascular System					1.0000
Cardiovascular	23	0.0181	1	0.0013	0.0010
Vision	26	0.0051	7	0.0091	0.1354
Any of the Above	467	0.3706	97	0.1337	0.0000
Total Patients Assessed	1680		802		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_10.SAS

Creation Date, Time: 17DEC04 10:24

(a) Time from implant surgery to first occurrence of event.

(b) Excludes data on revision patients.

(c) Based on Kaplan-Meier estimates.

(d) p-value is from log-rank test of estimated proportion among patients in SPS versus CoreGel.

Note: Sign/System categories were reviewed and approved by the FDA for the SPS report

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 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)  
AUGMENTATION PATIENTS

Sign/Symptom	36 Months after Implant Surgery				P-value (c)
	SPS (a)		CoreGel		
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	
LOSS OF WEIGHT WITHOUT DIETING	15	0.0160	2	0.0044	0.0625
FATIGUE	91	0.0948	9	0.0177	0.0000
INSOMNIA	61	0.0653	8	0.0153	0.0002
WEAKNESS	36	0.0035	4	0.0075	0.0619
EXHAUSTION	37	0.0388	5	0.0100	0.0017
JOINT SWELLING	21	0.0017	7	0.0141	0.0000
HEEL PAIN	8	0.0086	5	0.0108	0.8925
FREQUENT MUSCLE CRAMPS	28	0.0289	5	0.0100	0.0208
NUMBNESS OF FEET	14	0.0150	5	0.0100	0.4503
RINGING IN EARS	19	0.0201	7	0.0140	0.4246
PAIN/GRITTIENESS IN EYES	8	0.0040	3	0.0055	0.6128
DRYNESS OF EYES/NOSE	30	0.0318	1	0.0019	0.0003
PAIN ON SWALLOWING OR CHEWING	5	0.0055	0	0.0000	0.0664
NECK PAIN/STIFFNESS	58	0.0619	9	0.0188	0.0001
PAIN ON BREATHING	3	0.0043	0	0.0000	0.2982
HEART MURMURS	20	0.0201	1	0.0018	0.0033
LOSS OF APPETITE	16	0.0174	1	0.0019	0.0292
PERSISTENT FEVER	1	0.0010	0	0.0000	0.5028
NIGHT SWEATS	33	0.0335	7	0.0143	0.0100
GENERALIZED ACHING	22	0.0231	5	0.0105	0.0889

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_11.SAS

Creation Date, Time: 17DEC04 10:16

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

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 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)  
AUGMENTATION PATIENTS

Sign/Symptom	36 Months after Implant Surgery				P-value (c)
	SPS (a)		CoreGel		
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	
LOSS OF HEIGHT	0	0.0000	0	0.0000	0.5241
JOINT PAIN	54	0.0192	13	0.0262	0.2356
FREQUENT MUSCLE PAIN	10	0.0035	3	0.0057	0.7790
NUMBNESS OF HANDS	26	0.0274	13	0.0266	0.5458
JAW PAIN	21	0.0209	0	0.0000	0.0006
OPEN SORES	1	0.0010	0	0.0000	0.4931
REDNESS OF EYES	9	0.0045	3	0.0063	0.9449
DRYNESS OF MOUTH	15	0.0156	1	0.0019	0.0213
BACK PAIN/STIFFNESS	72	0.0754	6	0.0114	0.0000
SEVERE CHEST PAINS	1	0.0010	2	0.0037	0.2018
CHRONIC COUGH	4	0.0039	2	0.0038	0.6876
DIFFICULTY SWALLOWING	5	0.0059	0	0.0000	0.1660
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	27	0.0280	3	0.0062	0.0053
SEVERE RASHES	4	0.0014	3	0.0056	0.1520
SEVERE DRYNESS OF SKIN	23	0.0247	3	0.0068	0.0278
TENDER LUMPS/BUMPS	8	0.0030	1	0.0019	0.4387
EXCESSIVE SENSITIVITY TO SUN	10	0.0106	0	0.0000	0.0258
COLOR CHANGES ON HANDS/FEET WITH COLD EX	26	0.0141	0	0.0000	0.0065
FREQUENT HIVES	3	0.0030	1	0.0020	0.2995
TIGHTNESS OF SKIN	0	0.0000	0	0.0000	0.6689

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_11.SAS

Creation Date, Time: 17DEC04 10.16

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

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 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)  
AUGMENTATION PATIENTS

Sign/Symptom	36 Months after Implant Surgery				P-value (c)
	SPS (a)		CoreGel		
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	
UNUSUAL HAIR LOSS	30	0.0159	3	0.0069	0.0712
TENDERNESS OF SCALP	7	0.0069	0	0.0000	0.0485
SEVERE BRUISING WITH LITTLE OR NO INJURY	14	0.0147	2	0.0043	0.0606
COMBINED FATIGUE	119	0.1238	10	0.0195	0.0000
COMBINED PAIN	161	0.1683	20	0.0391	0.0000
COMBINED FIBROMYALGIA	79	0.0815	8	0.0152	0.0000
Any of the Above	329	0.3336	53	0.1030	0.0000
Total Patients Assessed	1264		551		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_11.SAS

Creation Date, Time: 17DEC04 10:16

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

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 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)  
RECONSTRUCTION PATIENTS

Sign/Symptom	36 Months after Implant Surgery				P-value (c)
	SPS (a)		CoreGel		
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	
LOSS OF WEIGHT WITHOUT DIETING	9	0.0462	1	0.0043	0.1220
FATIGUE	42	0.1635	7	0.0371	0.0014
INSOMNIA	22	0.0833	4	0.0214	0.0231
WEAKNESS	31	0.0117	4	0.0215	0.0418
EXHAUSTION	25	0.1061	2	0.0090	0.0035
JOINT SWELLING	28	0.0085	10	0.0449	0.0000
HEEL PAIN	9	0.0354	2	0.0130	0.1865
FREQUENT MUSCLE CRAMPS	20	0.0760	8	0.0351	0.4258
NUMBNESS OF FEET	9	0.0379	0	0.0000	0.0402
RINGING IN EARS	6	0.0247	1	0.0046	0.1719
PAIN/GRITTIENESS IN EYES	2	0.0035	2	0.0084	0.3022
DRYNESS OF EYES/NOSE	14	0.0535	2	0.0084	0.0504
PAIN ON SWALLOWING OR CHEWING	1	0.0034	0	0.0000	0.3643
NECK PAIN/STIFFNESS	24	0.0851	4	0.0299	0.0149
PAIN ON BREATHING	2	0.0095	0	0.0000	0.2758
HEART MURMURS	3	0.0103	0	0.0000	0.1585
LOSS OF APPETITE	10	0.0424	0	0.0000	0.0253
PERSISTENT FEVER	2	0.0069	0	0.0000	0.3415
NIGHT SWEATS	33	0.1353	5	0.0277	0.0029
GENERALIZED ACHING	17	0.0653	3	0.0130	0.0361

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_11.SAS

Creation Date, Time: 17DEC04 10:16

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)  
RECONSTRUCTION PATIENTS

Sign/Symptom	36 Months after Implant Surgery				P-value (c)
	SPS (a)		CoreGel		
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	
LOSS OF HEIGHT	6	0.0324	4	0.0175	0.9362
JOINT PAIN	41	0.0587	17	0.0798	0.0017
FREQUENT MUSCLE PAIN	11	0.0127	4	0.0175	0.5100
NUMBNESS OF HANDS	20	0.0845	0	0.0000	0.0019
JAW PAIN	3	0.0155	1	0.0084	0.7904
OPEN SORES	0	0.0000	0	0.0000	
REDNESS OF EYES	7	0.0123	0	0.0000	0.1866
DRYNESS OF MOUTH	14	0.0675	0	0.0000	0.0094
BACK PAIN/STIFFNESS	20	0.0859	3	0.0127	0.0283
SEVERE CHEST PAINS	1	0.0035	0	0.0000	0.3849
CHRONIC COUGH	5	0.0233	0	0.0000	0.1304
DIFFICULTY SWALLOWING	2	0.0068	0	0.0000	0.2609
FREQUENT, SEVERE DIARRHEA/CONSTIPATION	17	0.0650	1	0.0084	0.0288
SEVERE RASHES	2	0.0058	0	0.0000	0.6207
SEVERE DRYNESS OF SKIN	16	0.0562	0	0.0000	0.0034
TENDER LUMPS/BUMPS	5	0.0058	1	0.0068	0.8150
EXCESSIVE SENSITIVITY TO SUN	3	0.0106	0	0.0000	0.1152
COLOR CHANGES ON HANDS/FEET WITH COLD EX	8	0.0172	0	0.0000	0.1754
FREQUENT HIVES	0	0.0000	0	0.0000	
TIGHTNESS OF SKIN	4	0.0072	0	0.0000	0.3341

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_11 SAS

Creation Date, Time: 17DEC04 10:16

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

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 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)  
RECONSTRUCTION PATIENTS

Sign/Symptom	36 Months after Implant Surgery				P-value (c)
	SPS (a)		CoreGel		
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	
UNUSUAL HAIR LOSS	15	0.0314	2	0.0124	0.3821
TENDERNESS OF SCALP	2	0.0084	1	0.0043	0.9653
SEVERE BRUISING WITH LITTLE OR NO INJURY	7	0.0303	1	0.0047	0.1149
COMBINED FATIGUE	58	0.2172	10	0.0501	0.0002
COMBINED PAIN	77	0.2862	27	0.1344	0.0222
COMBINED FIBROMYALGIA	41	0.1439	8	0.0376	0.0050
Any of the Above	138	0.5025	44	0.2149	0.0004
Total Patients Assessed	416		251		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_11.SAS

Creation Date, Time. 17DEC04 10:16

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

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 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)  
REVISION PATIENTS

Sign/Symptom	36 Months after Implant Surgery				P-value (c)
	SPS (a)		CoreGel		
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	
LOSS OF WEIGHT WITHOUT DIETING	0	0.0000	3	0.0156	
FATIGUE	0	0.0000	11	0.0595	
INSOMNIA	0	0.0000	5	0.0258	
WEAKNESS	0	0.0000	6	0.0324	
EXHAUSTION	0	0.0000	6	0.0327	
JOINT SWELLING	0	0.0000	9	0.0522	
HEEL PAIN	0	0.0000	2	0.0099	
FREQUENT MUSCLE CRAMPS	0	0.0000	5	0.0278	
NUMBNESS OF FEET	0	0.0000	4	0.0225	
RINGING IN EARS	0	0.0000	5	0.0267	
PAIN/GRITTIENESS IN EYES	0	0.0000	0	0.0000	
DRYNESS OF EYES/NOSE	0	0.0000	2	0.0102	
PAIN ON SWALLOWING OR CHEWING	0	0.0000	2	0.0107	
NECK PAIN/STIFFNESS	0	0.0000	4	0.0202	
PAIN ON BREATHING	0	0.0000	1	0.0053	
HEART MURMURS	0	0.0000	0	0.0000	
LOSS OF APPETITE	0	0.0000	2	0.0106	
PERSISTENT FEVER	0	0.0000	0	0.0000	
NIGHT SWEATS	0	0.0000	4	0.0200	
GENERALIZED ACHING	0	0.0000	7	0.0387	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_11.SAS

Creation Date, Time: 17DEC04 10:16

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

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Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)  
REVISION PATIENTS

Sign/Symptom	36 Months after Implant Surgery				P-value (c)
	SPS (a)		CoreGel		
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	
LOSS OF HEIGHT	0	0.0000	1	0.0053	
JOINT PAIN	0	0.0000	14	0.0731	
FREQUENT MUSCLE PAIN	0	0.0000	3	0.0152	
NUMBNESS OF HANDS	0	0.0000	8	0.0431	
JAW PAIN	0	0.0000	1	0.0050	
OPEN SORES	0	0.0000	0	0.0000	
REDNESS OF EYES	0	0.0000	2	0.0107	
DRYNESS OF MOUTH	0	0.0000	2	0.0103	
BACK PAIN/STIFFNESS	0	0.0000	8	0.0469	
SEVERE CHEST PAINS	0	0.0000	0	0.0000	
CHRONIC COUGH	0	0.0000	0	0.0000	
DIFFICULTY SWALLOWING	0	0.0000	2	0.0107	
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	0	0.0000	4	0.0204	
SEVERE RASHES	0	0.0000	0	0.0000	
SEVERE DRYNESS OF SKIN	0	0.0000	5	0.0328	
TENDER LUMPS/BUMPS	0	0.0000	5	0.0269	
EXCESSIVE SENSITIVITY TO SUN	0	0.0000	1	0.0050	
COLOR CHANGES ON HANDS/FEET WITH COLD EX	0	0.0000	2	0.0099	
FREQUENT HIVES	0	0.0000	1	0.0049	
TIGHTNESS OF SKIN	0	0.0000	0	0.0000	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_11.SAS

Creation Date, Time: 17DEC04 10.16

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)  
REVISION PATIENTS

Sign/Symptom	36 Months after Implant Surgery				P-value (c)
	SPS (a)		CoreGel		
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	
UNUSUAL HAIR LOSS	0	0.0000	4	0.0237	
TENDERNESS OF SCALP	0	0.0000	1	0.0049	
SEVERE BRUISING WITH LITTLE OR NO INJURY	0	0.0000	4	0.0220	
COMBINED FATIGUE	0	0.0000	12	0.0644	
COMBINED PAIN	0	0.0000	19	0.1015	
COMBINED FIBROMYALGIA	0	0.0000	8	0.0407	
Any of the Above	0	0.0000	39	0.2128	
Total Patients Assessed	0		205		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_11.SAS

Creation Date, Time: 17DEC04 10:16

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 11.11

A COMPARISON BETWEEN COREGEL AND SPS OF CUMULATIVE INCIDENCE OF PATIENT REPORTED NEW POSTOPERATIVE POTENTIAL  
RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)  
OVERALL PATIENTS

Sign/Symptom	36 Months after Implant Surgery				P-value (c)
	SPS (a)		CoreGel		
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	
LOSS OF WEIGHT WITHOUT DIETING	24	0.0206	6	0.0068	0.0454
FATIGUE	133	0.1089	27	0.0304	0.0000
INSOMNIA	83	0.0700	17	0.0186	0.0000
WEAKNESS	67	0.0052	14	0.0155	0.0000
EXHAUSTION	62	0.0513	13	0.0146	0.0001
JOINT SWELLING	49	0.0031	26	0.0295	0.0000
HEEL PAIN	17	0.0141	9	0.0109	0.3273
FREQUENT MUSCLE CRAMPS	48	0.0391	18	0.0198	0.0364
NUMBNESS OF FEET	23	0.0195	9	0.0105	0.2119
RINGING IN EARS	25	0.0212	13	0.0147	0.3594
PAIN/GRITTIENESS IN EYES	10	0.0039	5	0.0051	0.5627
DRYNESS OF EYES/NOSE	44	0.0366	5	0.0052	0.0000
PAIN ON SWALLOWING OR CHEWING	6	0.0051	2	0.0022	0.1775
NECK PAIN/STIFFNESS	82	0.0683	17	0.0206	0.0000
PAIN ON BREATHING	5	0.0054	1	0.0011	0.2804
HEART MURMURS	23	0.0181	1	0.0010	0.0002
LOSS OF APPETITE	26	0.0222	3	0.0032	0.0032
PERSISTENT FEVER	3	0.0023	0	0.0000	0.1892
NIGHT SWEATS	66	0.0534	16	0.0181	0.0000
GENERALIZED ACHING	39	0.0318	15	0.0174	0.0477

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_11.SAS

Creation Date, Time: 17DEC04 10:16

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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Table 11.11

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RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)  
OVERALL PATIENTS

Sign/Symptom	36 Months after Implant Surgery				P-value (c)
	SPS (a)		CoreGel		
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	
LOSS OF HEIGHT	6	0.0055	5	0.0052	0.9880
JOINT PAIN	95	0.0268	44	0.0483	0.0000
FREQUENT MUSCLE PAIN	21	0.0056	10	0.0104	0.2442
NUMBNESS OF HANDS	46	0.0384	21	0.0243	0.0778
JAW PAIN	24	0.0190	2	0.0025	0.0005
OPEN SORES	1	0.0007	0	0.0000	0.4371
REDNESS OF EYES	16	0.0063	5	0.0058	0.7224
DRYNESS OF MOUTH	29	0.0249	3	0.0032	0.0006
BACK PAIN/STIFFNESS	92	0.0767	17	0.0192	0.0000
SEVERE CHEST PAINS	2	0.0015	2	0.0021	0.8915
CHRONIC COUGH	9	0.0072	2	0.0021	0.1175
DIFFICULTY SWALLOWING	7	0.0065	2	0.0022	0.3193
FREQUENT, SEVERE DIARRHEA/CONSTIPATION	44	0.0358	8	0.0092	0.0007
SEVERE RASHES	6	0.0019	3	0.0032	0.4307
SEVERE DRYNESS OF SKIN	39	0.0323	8	0.0107	0.0020
TENDER LUMPS/BUMPS	13	0.0038	7	0.0079	0.1526
EXCESSIVE SENSITIVITY TO SUN	13	0.0110	1	0.0010	0.0069
COLOR CHANGES ON HANDS/FEET WITH COLD EX	34	0.0148	2	0.0020	0.0059
FREQUENT HIVES	3	0.0023	2	0.0022	0.4446
TIGHTNESS OF SKIN	4	0.0016	0	0.0000	0.2434

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_11.SAS

Creation Date, Time: 17DEC04 10:16

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
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RHEUMATOLOGIC SYMPTOMS OR PHYSICAL EXAMINATION FINDINGS BY SIGN/SYMPTOM - FDA Item 7b(1)  
OVERALL PATIENTS

Sign/Symptom	36 Months after Implant Surgery				P-value (c)
	SPS (a)		CoreGel		
	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	Number with Sign/Symptom	Estimated Proportion with Sign/Symptom (b)	
UNUSUAL HAIR LOSS	45	0.0189	9	0.0115	0.1338
TENDERNESS OF SCALP	9	0.0071	2	0.0020	0.1208
SEVERE BRUISING WITH LITTLE OR NO INJURY	21	0.0176	7	0.0082	0.0605
COMBINED FATIGUE	177	0.1442	32	0.0355	0.0000
COMBINED PAIN	238	0.1947	66	0.0727	0.0000
COMBINED FIBROMYALGIA	120	0.0965	24	0.0254	0.0000
Any of the Above	467	0.3706	136	0.1500	0.0000
Total Patients Assessed	1680		1007		

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_11.SAS

Creation Date, Time: 17DEC04 10:16

(a) SPS does not have revision patients.

(b) Based on Kaplan-Meier estimates.

(c) p-value is from log-rank test of estimated proportion with symptom type among patients in SPS versus CoreGel.

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 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Sign/Symptom			
LOSS OF WEIGHT WITHOUT DIETING	Baseline	4/1007 (0.40)	0.8250
	1 Year	4/ 965 (0.41)	.
	2 Year	5/ 941 (0.53)	.
	3 Year	2/ 665 (0.30)	.
FATIGUE	Baseline	8/1007 (0.79)	0.0002
	1 Year	17/ 965 (1.76)	.
	2 Year	26/ 941 (2.76)	.
	3 Year	15/ 665 (2.26)	.
INSOMNIA	Baseline	24/1007 (2.38)	0.6084
	1 Year	22/ 965 (2.28)	.
	2 Year	26/ 941 (2.76)	.
	3 Year	10/ 665 (1.50)	.
WEAKNESS	Baseline	4/1007 (0.40)	0.0727
	1 Year	6/ 965 (0.62)	.
	2 Year	12/ 941 (1.28)	.
	3 Year	7/ 665 (1.05)	.
EXHAUSTION	Baseline	1/1007 (0.10)	0.0057
	1 Year	2/ 965 (0.21)	.
	2 Year	12/ 941 (1.28)	.
	3 Year	7/ 665 (1.05)	.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T11\_12.SAS

Creation Date, Time. 17DEC04 09:59

(1) p-value is from GEE model for the effect of the implant (year 1-3 visits versus baseline), adjusting for the age effect

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 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

Parameter	Visit	Number of Patients	p-value (1)
		With Event n/N(%)	
JOINT SWELLING	Baseline	12/1007 (1.19)	0.2164
	1 Year	15/ 965 (1.55)	.
	2 Year	21/ 941 (2.23)	.
	3 Year	10/ 665 (1.50)	.
HEEL PAIN	Baseline	2/1007 (0.20)	0.0138
	1 Year	4/ 965 (0.41)	.
	2 Year	8/ 941 (0.85)	.
	3 Year	7/ 665 (1.05)	.
FREQUENT MUSCLE CRAMPS	Baseline	3/1007 (0.30)	0.0009
	1 Year	8/ 965 (0.83)	.
	2 Year	17/ 941 (1.81)	.
	3 Year	9/ 665 (1.35)	.
NUMBNESS OF FEET	Baseline	2/1007 (0.20)	0.0278
	1 Year	4/ 965 (0.41)	.
	2 Year	8/ 941 (0.85)	.
	3 Year	5/ 665 (0.75)	.
RINGING IN EARS	Baseline	992/1007 (98.5)	0.0082
	1 Year	963/ 965 (99.8)	.
	2 Year	934/ 941 (99.3)	.
	3 Year	659/ 665 (99.1)	.
PAIN/GRITTIENESS IN EYES	Baseline	1/1007 (0.10)	0.1063
	1 Year	5/ 965 (0.52)	.

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Table 11.12

GEE MODEL TESTING THE EFFECT OF THE IMPLANT (YEAR 1-3 VISITS VERSUS BASELINE) ADJUSTING FOR THE AGE EFFECT - FDA Item 7b(2)

Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
PAIN/GRITTIENESS IN EYES	2 Year	5/ 941 (0.53)	.
	3 Year	2/ 665 (0.30)	.
DRYNESS OF EYES/NOSE	Baseline	14/1007 (1.39)	0.0529
	1 Year	12/ 965 (1.24)	.
	2 Year	13/ 941 (1.38)	.
	3 Year	3/ 665 (0.45)	.
PAIN ON SWALLOWING OR CHEWING	Baseline	1/1007 (0.10)	0.5139
	1 Year	1/ 965 (0.10)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	1/ 665 (0.15)	.
NECK PAIN/STIFFNESS	Baseline	18/1007 (1.79)	0.6354
	1 Year	18/ 965 (1.87)	.
	2 Year	17/ 941 (1.81)	.
	3 Year	11/ 665 (1.65)	.
PAIN ON BREATHING	Baseline	0/1007 ( 0)	.
	1 Year	0/ 965 ( 0)	.
	2 Year	1/ 941 (0.11)	.
	3 Year	0/ 665 ( 0)	.
HEART MURMURS	Baseline	23/1007 (2.28)	0.0006
	1 Year	18/ 965 (1.87)	.
	2 Year	15/ 941 (1.59)	.
	3 Year	4/ 665 (0.60)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
LOSS OF APPETITE	Baseline	1/1007 (0.10)	0.2389
	1 Year	1/ 965 (0.10)	.
	2 Year	4/ 941 (0.43)	.
	3 Year	2/ 665 (0.30)	.
PERSISTENT FEVER	Baseline	0/1007 ( 0)	.
	1 Year	0/ 965 ( 0)	.
	2 Year	0/ 941 ( 0)	.
	3 Year	0/ 665 ( 0)	.
NIGHT SWEATS	Baseline	16/1007 (1.59)	0.6123
	1 Year	20/ 965 (2.07)	.
	2 Year	14/ 941 (1.49)	.
	3 Year	7/ 665 (1.05)	.
GENERALIZED ACHING	Baseline	7/1007 (0.70)	0.0309
	1 Year	8/ 965 (0.83)	.
	2 Year	19/ 941 (2.02)	.
	3 Year	10/ 665 (1.50)	.
LOSS OF HEIGHT	Baseline	2/1007 (0.20)	0.1928
	1 Year	4/ 965 (0.41)	.
	2 Year	6/ 941 (0.64)	.
	3 Year	2/ 665 (0.30)	.
JOINT PAIN	Baseline	14/1007 (1.39)	<.0001
	1 Year	27/ 965 (2.80)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
JOINT PAIN	2 Year	40/ 941 (4.25)	.
	3 Year	24/ 665 (3.61)	.
FREQUENT MUSCLE PAIN	Baseline	7/1007 (0.70)	0.4309
	1 Year	11/ 965 (1.14)	.
	2 Year	13/ 941 (1.38)	.
	3 Year	4/ 665 (0.60)	.
NUMBNESS OF HANDS	Baseline	10/1007 (0.99)	0.0870
	1 Year	11/ 965 (1.14)	.
	2 Year	21/ 941 (2.23)	.
	3 Year	14/ 665 (2.11)	.
JAW PAIN	Baseline	6/1007 (0.60)	0.2939
	1 Year	6/ 965 (0.62)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	2/ 665 (0.30)	.
OPEN SORES	Baseline	0/1007 ( 0)	.
	1 Year	0/ 965 ( 0)	.
	2 Year	0/ 941 ( 0)	.
	3 Year	0/ 665 ( 0)	.
REDNESS OF EYES	Baseline	3/1007 (0.30)	0.2080
	1 Year	3/ 965 (0.31)	.
	2 Year	8/ 941 (0.85)	.
	3 Year	4/ 665 (0.60)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
DRYNESS OF MOUTH	Baseline	3/1007 (0.30)	0.9686
	1 Year	2/ 965 (0.21)	.
	2 Year	4/ 941 (0.43)	.
	3 Year	3/ 665 (0.45)	.
BACK PAIN/STIFFNESS	Baseline	18/1007 (1.79)	0.8495
	1 Year	18/ 965 (1.87)	.
	2 Year	27/ 941 (2.87)	.
	3 Year	10/ 665 (1.50)	.
SEVERE CHEST PAINS	Baseline	0/1007 ( 0)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	2/ 941 (0.21)	.
	3 Year	1/ 665 (0.15)	.
CHRONIC COUGH	Baseline	1/1007 (0.10)	.
	1 Year	0/ 965 ( 0)	.
	2 Year	2/ 941 (0.21)	.
	3 year	2/ 665 (0.30)	.
DIFFICULTY SWALLOWING	Baseline	0/1007 ( 0)	.
	1 Year	0/ 965 ( 0)	.
	2 Year	2/ 941 (0.21)	.
	3 Year	1/ 665 (0.15)	.
FREQUENT,SEVERE DIARRHEA/CONSTIPATION	Baseline	8/1007 (0.79)	0.7541
	1 Year	8/ 965 (0.83)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
FREQUENT, SEVERE DIARRHEA/CONSTIPATION	2 Year	9/ 941 (0.96)	.
	3 Year	7/ 665 (1.05)	.
SEVERE RASHES	Baseline	1/1007 (0.10)	.
	1 Year	2/ 965 (0.21)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	0/ 665 ( 0)	.
SEVERE DRYNESS OF SKIN	Baseline	2/1007 (0.20)	0.0170
	1 Year	5/ 965 (0.52)	.
	2 Year	7/ 941 (0.74)	.
	3 Year	4/ 665 (0.60)	.
TENDER LUMPS/BUMPS	Baseline	1/1007 (0.10)	0.0291
	1 Year	3/ 965 (0.31)	.
	2 Year	7/ 941 (0.74)	.
	3 Year	3/ 665 (0.45)	.
EXCESSIVE SENSITIVITY TO SUN	Baseline	3/1007 (0.30)	0.9793
	1 Year	3/ 965 (0.31)	.
	2 Year	4/ 941 (0.43)	.
	3 Year	2/ 665 (0.30)	.
COLOR CHANGES ON HANDS/FEET WITH COLD EXPOSURE	Baseline	10/1007 (0.99)	0.8655
	1 Year	9/ 965 (0.93)	.
	2 Year	10/ 941 (1.06)	.
	3 Year	7/ 665 (1.05)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
FREQUENT HIVES	Baseline	1/1007 (0.10)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	2/ 941 (0.21)	.
	3 Year	0/ 665 ( 0)	.
TIGHTNESS OF SKIN	Baseline	1/1007 (0.10)	.
	1 Year	1/ 965 (0.10)	.
	2 Year	0/ 941 ( 0)	.
	3 Year	0/ 665 ( 0)	.
UNUSUAL HAIR LOSS	Baseline	4/1007 (0.40)	0.1381
	1 Year	5/ 965 (0.52)	.
	2 Year	7/ 941 (0.74)	.
	3 Year	9/ 665 (1.35)	.
TENDERNESS OF SCALP	Baseline	1/1007 (0.10)	0.5785
	1 Year	2/ 965 (0.21)	.
	2 Year	2/ 941 (0.21)	.
	3 Year	2/ 665 (0.30)	.
SEVERE BRUISING WITH LITTLE OR NO INJURY	Baseline	8/1007 (0.79)	0.8378
	1 Year	8/ 965 (0.83)	.
	2 Year	8/ 941 (0.85)	.
	3 Year	5/ 665 (0.75)	.
COMBINED FATIGUE	Baseline	11/1007 (1.09)	0.0020
	1 Year	20/ 965 (2.07)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
COMBINED FATIGUE	2 Year	30/ 941 (3.19)	.
	3 Year	15/ 665 (2.26)	.
COMBINED PAIN	Baseline	45/1007 (4.47)	0.1364
	1 Year	56/ 965 (5.80)	.
	2 Year	67/ 941 (7.12)	.
	3 Year	33/ 665 (4.96)	.
COMBINED FIBROMYALGIA	Baseline	6/1007 (0.60)	0.0006
	1 Year	13/ 965 (1.35)	.
	2 Year	23/ 941 (2.44)	.
	3 Year	12/ 665 (1.80)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Sign/Symptom Category			
Skin and Appendages	Baseline	8/1007 (0.79)	0.0049
	1 Year	13/ 965 (1.35)	.
	2 Year	17/ 941 (1.81)	.
	3 Year	13/ 665 (1.95)	.
Muscle	Baseline	42/1007 (4.17)	0.7587
	1 Year	43/ 965 (4.46)	.
	2 Year	53/ 941 (5.63)	.
	3 Year	27/ 665 (4.06)	.
Joint	Baseline	22/1007 (2.18)	0.0011
	1 Year	36/ 965 (3.73)	.
	2 Year	49/ 941 (5.21)	.
	3 Year	26/ 665 (3.91)	.
CNS	Baseline	34/1007 (3.38)	0.3973
	1 Year	34/ 965 (3.52)	.
	2 Year	47/ 941 (4.99)	.
	3 Year	22/ 665 (3.31)	.
Gastrointestinal	Baseline	8/1007 (0.79)	0.4879
	1 Year	8/ 965 (0.83)	.
	2 Year	11/ 941 (1.17)	.
	3 Year	8/ 665 (1.20)	.

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Parameter	Visit	Number of Patients With Event n/N(%)	p-value (1)
Body as a Whole	Baseline	54/1007 (5.36)	0.5856
	1 Year	60/ 965 (6.22)	.
	2 Year	71/ 941 (7.55)	.
	3 Year	35/ 665 (5.26)	.
Metabolic and Nutritional	Baseline	4/1007 (0.40)	0.8250
	1 Year	4/ 965 (0.41)	.
	2 Year	5/ 941 (0.53)	.
	3 Year	2/ 665 (0.30)	.
Hearing and Vestibular	Baseline	992/1007 (98.5)	0.0082
	1 Year	963/ 965 (99.8)	.
	2 Year	934/ 941 (99.3)	.
	3 Year	659/ 665 (99.1)	.
Respiratory	Baseline	1/1007 (0.10)	.
	1 Year	0/ 965 ( 0)	.
	2 Year	3/ 941 (0.32)	.
	3 Year	2/ 665 (0.30)	.
Platelet, Bleeding, Clotting Disorder	Baseline	8/1007 (0.79)	0.8378
	1 Year	8/ 965 (0.83)	.
	2 Year	8/ 941 (0.85)	.
	3 Year	5/ 665 (0.75)	.
Cardiovascular	Baseline	23/1007 (2.28)	0.0006
	1 Year	18/ 965 (1.87)	.

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Parameter	Visit	Number of Patients	p-value (1)
		With Event n/N(%)	
Cardiovascular	2 Year	15/ 941 (1.59)	.
	3 Year	4/ 665 (0.60)	.
Vision	Baseline	3/1007 (0.30)	0.0209
	1 Year	7/ 965 (0.73)	.
	2 Year	12/ 941 (1.28)	.
	3 Year	5/ 665 (0.75)	.