

9. For the Kaplan-Meier data, please provide the additional information/revisions below.

a. Please include all MRI suspected ruptures in these data.

9a Response:

The Kaplan-Meier data has been modified to include suspected ruptures and the results are presented in Tables 8.7.1 and 8.7.2 in the attached 3-Year Core Gel Clinical Study Update. The overall rupture rate is 0.7% by-patient and 0.5% by-implant.

b. Please present nipple sensitivity complications in the category of “nipple sensation changes.” It is not acceptable to exclude “nipple-unacceptably low sensitivity” as stated in your footnote. These data should include all but mild increases and decreases in nipple sensation.

9b Response:

Nipple sensitivity complications have been re-categorized as “nipple sensation changes.” For clarification, as stated in the referenced footnote, only mild cases (as determined by the Investigator) of reported complications, including “nipple-unacceptably low

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sensitivity” were excluded from Table 8.7.1 and 8.7.2 in the attached 3-Year Core Gel Clinical Study Update.

- c. **Please present breast sensitivity complications in the category of “breast sensation changes.” It is not acceptable to exclude “breast-unacceptably low/high sensitivity” as stated in your footnote. These data should include all but mild increases and decreases in breast sensation.**

9c Response:

Breast sensitivity complications have been re-categorized as “breast sensation changes.” For clarification, as stated in the referenced footnote, only mild cases (as determined by the Investigator) of reported complications, including “breast-unacceptably low sensitivity” were excluded from Table 8.7.1 and 8.7.2 in the attached 3-Year Core Gel Clinical Study Update.

- d. **Please recategorize “position change,” which is a procedure rather than a complication, into “implant malposition/displacement.” In addition, it is not clear how there is a mild case of implant malposition/displacement. Please clarify. Otherwise, include all cases of implant malposition/displacement in these data sets.**

9d Response:

Position change was recategorized and is reflected in Tables 8.7.1 and 8.7.2 in the attached 3-Year Core Gel Clinical Study Update. For each complication, the Investigator, not Mentor, defines the severity, based on his/her professional judgment. There is only one case of mild “implant malposition/displacement.” In this instance, the Investigator reported the severity as “mild” on the Case Report Form.

- e. **One of your complications is identified as “breast pain not associated with any other complication.” FDA does not believe it is appropriate to exclude breast pain from being reported just because it is associated with another complication. Therefore, please rename this complication to be called “breast pain” and include all but mild cases of breast pain, whether or not, it is associated with another complication.**

9e Response:

Breast pain not associated with any other complication was recategorized, and all cases but mild are reflected in Tables 8.7.1 and 8.7.2 in the attached 3-Year Core Gel Clinical Study Update.

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- f. **Please combine “explant with replacement” and “explant without replacement” into a single category of “removal with or without replacement.”**

9f Response:

The requested information was recategorized and is reflected in Tables 8.7.1 and 8.7.2 in the attached 3-Year Core Gel Clinical Study Update.

- g. **“Patient dissatisfied with appearance,” “patient requested size change,” and “physician assessment size change” are not considered complications. Please re-categorize these into actual complications (e.g., removal with or without replacement).**

9g Response:

The requested information was recategorized and is reflected in Tables 8.7.1 and 8.7.2 in the attached 3-Year Core Gel Clinical Study Update.

- h. **Please identify the complications involved in “surgical complications” rather than use this term.**

9h Response:

In the Kaplan Meier Tables 8.7.1 and 8.7.2 in the attached 3-Year Core Gel Clinical Study Update, the surgical complications are specifically identified.

10. For the types of additional surgical procedures data, please provide the additional revisions/information below

- a. **Please include all MRI suspected ruptures in these data.**
- b. **Please move “open capsulectomy” into the existing “capsulectomy” category.**
- c. **Please combine “closed capsulotomy” and “open capsulotomy” into one category of “capsulotomy” with a footnote specifying the number of closed capsulotomies.**
- d. **Hematoma is not considered a procedure. Please recategorize this into the actual procedure (e.g., hematoma evacuation).**
- e. **Please recategorize “implant removal with replacement other than size change” into “implant removal with replacement.”**
- f. **Implant size change is not considered a procedure. Please recategorize this into the actual procedure (e.g., implant removal with replacement).**
- g. **Please re-categorize “position change” into “implant reposition.”**

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- h. Please clarify if the Kenalog injection was to the pocket or to implant.**
- i. Please combine “nipple elevation,” “nipple reduction,” and “left nipple revision” into one category of “nipple related procedures (unplanned).”**
- j. Please explain “revision of breast/external to pocket.”**

10a, b, c, d, e, f, g, i Response:

Table 9.1 in the attached 3-Year Core Gel Clinical Study Update has been modified in accordance with Items 10a, 10b, 10c, 10d, 10e, 10f, 10g, and 10i above.

10h Response:

For patient 430-031, the Kenalog injection was the treatment for hypertrophic scarring, and was not placed in either the implant or the pocket. The Kenalog injection was removed from all complication tables, as it is a treatment and not a complication.

10j Response:

Patient 440.001 reported “revision of breast/external to pocket.” The reoperation occurred on 7/16/2002 involving both implants. The reason reported on the CRF was capsulorrhaphy and suction revision of the axillary breast tissue.

11. For the reasons for reoperation data, please provide the additional revisions/information below.

- a. Please include all MRI suspected ruptures in these data.**
- b. Please combine “breast mass,” “right breast lump,” “lump,” “right breast mass,” and “breast mass not associated with implant” into one category of “breast mass.”**
- c. Please combine “breast lesions” and “skin lesions” to one category of “breast/skin lesions.”**
- d. Please combine “capsular contracture III/IV,” “capsular contracture III and staged reconstruction,” and “capsular contracture secondary to radiation therapy” into one category of “capsular contracture.”**
- e. Please combine “infection” and “infection and seroma” into one category of “infection” (you can add footnote).**
- f. Please combine “nipple and areolar reconstruction,” “nipple reconstruction with areolar graft,” and “re-do nipple reconstruction; breast mass not associated with implant” into one category of “nipple related (unplanned).”**

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- g. Please combine “patient dissatisfied with appearance,” “patient requests removal” and “size change” into one category of “patient request.”**
- h. Please recategorize “position change” and “excessive breast pain and position change” into “implant malposition/displacement.”**

11a-11h Response

The additional revisions/information data for 11a-11h have been incorporated in Table 9.2 in the attached 3-Year Core Gel Clinical Study Update.

- i. Please identify the complications involved in “surgical complications” rather than use this term.**

11i Response:

The complications involved in “surgical complications” are listed below:

Patient	Coded Complication	Actual complication
416.011	Surgical Complications	Symmastia
420.010	Surgical Complications	Extra skin bump
432.002	Surgical Complications	Tight bonilli suture

- j. Please explain “exposed implant re-sutured,” “suture reaction,” “tear in capsule,” and “false positive MRI for rupture.” If necessary, your explanation should include the procedure involved.**

11j Response:

The following explanations are provided for the four specified occurrences:

- Exposed implant re-sutured (Patient 450.006) was re-categorized as an extrusion.
- Suture Reaction (Patient 405.014) was re-categorized as a reaction to the vicryl suture.
- Tear in Capsule (Patient 407.011) was corrected to indicate a repair in capsule.
- False positive MRI for rupture (Patient 402.026) was re-categorized as a suspected rupture secondary to MRI.

All of these changes are reflected in Table 9.2 in the attached 3-Year Core Gel Clinical Study Update.

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- k. For the 3 reconstruction and 1 revision reasons for reoperation that are missing, please provide the procedures involved.**

11k Response:

A review of Table 9.2 submitted in the PMA reveals that there were 3 patients with missing reasons for reoperation. The reasons are provided below:

- Patient 410.057 (Reconstruction) had a capsulectomy procedure on 1/22/02.
- Patient 419.009 (Reconstruction) had a skin adjustment procedure on 11/16/01.
- Patient 419.023 (Reconstruction) had a skin adjustment procedure on 12/17/01.

All of these changes are reflected in Table 9.2 in the attached 3-Year Core Gel Clinical Study Update.

- 12. For the reasons for removal data, please provide the additional revisions/information below.**

- a. Please include all MRI suspected ruptures in these data.**

12a Response:

All MRI suspected rupture data are included in Tables 9.3.2 and 9.3.3 in the attached 3-Year Core Gel Clinical Study Update.

- b. Please combine “capsular contracture III/IV,” “capsular contracture III and staged reconstruction,” and “capsular contracture secondary to radiation therapy” into a category of “capsular contracture.”**

12b Response:

We have combined the above requested data into one category of capsular contracture in Tables 9.3.2 and 9.3.3 in the attached 3-Year Core Gel Clinical Study Update.

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c. Please explain “false positive MRI for rupture” and “muscle spasm.”

12c Response:

The following explanations are provided for the two specified occurrences:

- False positive MRI for rupture (Patient 402.026) was re-categorized as suspected rupture.
- Muscle spasm (Patient 419.004) was verified to be a hyperactive pectoralis muscle.

d. Please combine “patient dissatisfied with appearance,” “patient requests removal,” and “size change” into a category of “patient request.”

12d Response:

We have combined the above requested data into one category of patient request in Tables 9.3.2 and 9.3.3 in the attached 3-Year Core Gel Clinical Study Update.

e. Please identify the complications involved in “surgical complications” rather than use this term.

12e Response:

The surgical complication for Patient 416.011 was symmastia.

f. Please recategorize “position change” into “implant malposition/displacement.”

12f Response:

We have combined the above requested data into one category of implant malposition/displacement in Tables 9.3.2 and 9.3.3 in the attached 3-Year Core Gel Clinical Study Update.

13. When updating the Kaplan-Meier risk rates after removal with reimplantation, please make all applicable revisions requested for the Kaplan-Meier risk rates for the original patients, as per item 9 above.

13 Response:

For Kaplan Meier risk rates after removal with reimplantation, the same revisions have been made as per question 9. Please see Tables 8.18.1 and 8.18.2 in the attached 3-Year Core Gel Clinical Study Update.

14. Please provide a new set of tables for each indication that summarizes the primary surgical procedure performed for a given reoperation (cumulative presentation).

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14 Response:

A new set of tables that summarizes the primary surgical procedure performed for a given reoperation (cumulative presentation) is provided in Table 9.6 in the attached 3-Year Core Gel Clinical Study Update.

15. For those patients who had removal of all study implants during the Core Study, please provide the following information, stratified by indication:

a. the reason for explant of all study devices and the source of this information (i.e., which case report form);

15a Response:

The table in Attachment A of this report provides the reason for explant of study devices. Explant information is collected on the Secondary Procedures Report CRF.

b. the implant status (i.e., ruptured or non-ruptured) at the time of removal for those that led to patient discontinuation;

15b Response:

At the time of explant, all devices were intact (*i.e.*, non-ruptured), except for patient 404-015 (Revision).

c. whether and which of these patients were included in data tables describing implant removal;

15c Response:

All patients who were explanted had their data included in Tables 8.1 and 9.1 describing implant removal in the attached 3-Year Core Gel Clinical Study Update.

d. a description of the nature of complications reported by these patients and if the complications were resolved; and

15d Response:

The description of the nature of complications and resolution of these complications are included in the table in Attachment B of this report.

e. the reason(s) why the implants were not replaced, if available.

15e Response:

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The reasons why the implants were not replaced is not available, as this information is not requested on the Case Report Forms.

16. Please modify all other data tables provided for the Core Study as per items 9-12 above, as applicable (e.g., recategorization of line items).

16 Response:

All data tables have been modified per items 9-12 above and are provided in Tables 8.1 through 8.6.3 in the attached 3-Year Core Gel Clinical Study Update.