

5. Additional information regarding the patient accounting data for the MRI cohort is necessary. Please provide the information/clarifications below.

- a. Please provide the patient accounting (Table 13.3) on a by-implant basis and for each indication (i.e., augmentation, reconstruction, or revision) separately. When determining expected due, please exclude only those patients who had death or removal without replacement from theoretically due. Therefore, please include the 52 patients who were “unable to have MRI” in the expected due. Please rectify any discrepancies between the values in this revised information and the values reported in the three tables labeled Table 13.1 of Volume 3.**

5a Response:

Revised patient accounting by indication for patients enrolled into the MRI substudy is provided in Table 13.3.1 and by implant in Table 13.3.2 (implant level) in the attached 3-Year Core Gel Clinical Study Update. The 52 patients referred in question 5a, declined to participate in the MRI Substudy, and therefore are not included in the “Expected Due” category of patient accounting. A total of 472 patients were contacted, of which 420 agreed to participate, and 52 declined. For a discussion of MRI Substudy patient follow-up accounting, please see Response 1a.

- b. The three tables labeled Table 13.1 in Volume 3 indicate that data are provided for 404 patients overall. However, the patient accounting Table 13.3 indicates that data are provided for 340 patients at 1 year and for 326 patients at 2 years. Please rectify this discrepancy.**

5b Response:

There were a total of 420 patients overall that participated in the MRI substudy, but not all came in for their 1-year and 2-year scans. In the updated 3-year Core Gel Clinical report, of the 420 randomized patients, 326 (78%) came in for their 1 year scan and 372 (89%) came in for the 2-year scan.

- c. For those patients “unable to have an MRI,” please provide the reason(s) for this inability. In addition, please indicate how you intend to either collect these data or replace these patients.**

5c Response:

The 52 patients referenced in question 5c declined to participate in the MRI Substudy. Therefore none of them should have been included in Table 13.3 as “unable to have a MRI.” Table 13.3.1 in the attached 3-Year Core Gel Clinical Study Update accurately reflects this information.