

**November 17, 2006**

To: Adjunct Study Investigators

Re: Mentor Adjunct Study and FDA Approval of Mentor's PMA Application

Dear Doctor and Study Coordinator:

Following our initial communication regarding FDA's conditions of approval of our premarket approval application (PMA) for our MemoryGel™ implant products, we would like to review some of the important aspects specific to the Adjunct study, and provide you with templates you can use to communicate these important changes with your local IRB and Adjunct patients, who need to understand their continuing obligation to the Adjunct study.

Important Points Regarding the Adjunct Study:

1. Enrollment in the Mentor Adjunct study for MemoryGel round implants has now ceased.
2. You are required to continue to follow up with your enrolled patients, making every effort to bring them back for their 1, 3, and 5-year follow-up visits.
3. You must continue to report all adverse events.
4. Becker and Lumera products will no longer be available; however, FDA will allow investigators who are currently enrolled in the Mentor Adjunct study to continue with their Becker and Lumera implant surgeries, provided the paperwork has begun for the surgery. Note: these patients will be enrolled into the Mentor Adjunct study.
5. After a 90-day transition, Adjunct investigators will be required to complete Mentor's Device Access Education (DAE) Course in order to have access to the approved Mentor round silicone gel-filled breast implants. You can find the course at: [www.MemoryGel.com](http://www.MemoryGel.com).
6. There will be a 90-day transition period between approval and the implementation of all post-approval conditions, with the exception of new physician/patient labeling and Device Tracking, which will begin immediately.
7. There is important new physician and patient labeling that is part of our updated packaging, and can also be found on-line at [www.MemoryGel.com](http://www.MemoryGel.com).

We look forward to the transition to open market sales, appreciate your continued loyalty to Mentor, and value your contribution in bringing us to this exciting milestone.

Please contact your Mentor Clinical Research Associate at 800-258-3494 if you have any questions.

Thank you,

Rosalyn Cole, CCRP  
Program Manager, Adjunct study

**“IRB Chair Sample Letter”**

**November 17, 2006**

**[Insert Name of Investigational Review Board here]**

Re: Mentor Adjunct Study **[Insert study Reference number here]**

Dear **[INSERT NAME OF IRB CHAIR here]**:

We are proud to announce FDA approval of our premarket approval application (PMA) for our following breast implant products:

- Moderate Profile, MemoryGel™(Smooth and Textured Surface Shells)
- Moderate Plus Profile, MemoryGel™(Smooth and Textured Surface Shells)
- High Profile MemoryGel™(Smooth and Textured Surface Shells)

These products are approved for the following indications:

- **Breast augmentation for women at least 22 years old.** Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.
- **Breast reconstruction.** Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

As a condition of PMA approval, all new enrollment in the Mentor Adjunct study for MemoryGel round implants has now ceased. It is extremely important that physicians follow up with enrolled patients, and make every effort to bring them back for their 1, 3, and 5-year follow-up visits, and also to continue to report all adverse events.

Becker and Lumera products which were available through the Adjunct study will no longer be accessible; however, during a 90-day transition period, FDA will allow investigators who are currently enrolled in the Mentor Adjunct study to continue with their Becker and Lumera implant surgeries, provided the paperwork has begun for the surgery. Note: these patients will be enrolled into the Mentor Adjunct study. After the 90-day transition period, Mentor will collect any unused Lumera and Becker implants.

Another condition of PMA approval requires physicians to completed Mentor's Device Access Education (DAE) Course in order or access or implant approved MemoryGel™ Implants. Former investigators in the Adjunct study may access and implant MemoryGel™ Implants immediately, but are required to complete the DAE course within 90 of approval if they plan to continue to order or implant the devices.

The new product labeling is different from prior MemoryGel™ Implant information and must be reviewed prior to ordering or accessing MemoryGel™ Implants. The new patient and physician

labeling can be found at, [www.MemoryGel.com](http://www.MemoryGel.com), and is also found in the “Important New Labeling Information and Material” letter found in product with updated packaging.

Please contact your Mentor Clinical Research Assistant at 800-258-3494 if you have any questions.

Thank you,

Rosalyn Cole, CCRP  
Program Manager, Adjunct study

## “Adjunct Study Patient Sample Letter”

November 17, 2006

Dear Adjunct Study Patient:

It is my pleasure to inform you that Mentor’s MemoryGel™ breast implant(s) were approved by FDA for commercial distribution in the United States. The approved uses are as follows:

- **Breast augmentation for women at least 22 years old.** Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.
- **Breast reconstruction.** Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

This approval would not have been possible without your commitment to the Adjunct study, and while Mentor’s MemoryGel™ breast implants are “approved,” your commitment to this study is not yet complete.

We respectfully ask that you continue to honor your commitment to the study because this is one of the most important ways longer-term data can be gathered on Mentor’s MemoryGel™ breast implants. We will continue to collect the same data about you and your implant(s) for the duration of the 5-year study, and as spelled out in the original informed consent you signed, we ask that you return for postoperative visits at 1, 3, and 5 years, and report any adverse events you experience.

It is important that you review all new patient information in its entirety by accessing Mentor’s website at [www.Mentor4Me.com](http://www.Mentor4Me.com). Additional information can be found on FDA’s website at [www.fda.gov/cdrh/breastimplants](http://www.fda.gov/cdrh/breastimplants), or you may call Mentor at 1-800-MENTOR-8 with any other questions.

Mentor and I thank you again for your past and continued commitment to this important study.

Regards,

[Insert **Physician Name here**]