



the process of Acknowledgment of Informed Decision found at the very end of the patient brochures.

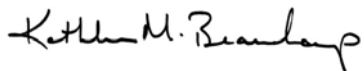
- For physicians who have not participated in a MemoryGel implant study, you are required to complete the DAE course prior to placing an order or accessing MemoryGel implants. Please refer to the “Device Access Education” letter included in this packet.
3. The FDA has determined that all physicians who use MemoryGel implants will have ongoing product tracking obligations. In addition to the training you will receive in the DAE course, we are providing you with instructions concerning tracking requirements (“Physician/Hospital/Surgery Center Device Tracking Requirements”). Please read these instructions carefully and in their entirety, as they describe your obligations that are required by law. We ask that you retain the “Physician Tracking Requirements” in your files to help you with your ongoing obligations. A sample of a “Device Tracking Form” is attached at the end of this packet. The “Physician Tracking Requirements” and additional Device Tracking Forms also are available on-line at [www.MemoryGel.com](http://www.MemoryGel.com), by calling our literature room at **1-800-525-0245 ext. 6442**, or through your Mentor sales representative.

In addition to Adjunct Study IRB and patient letters, please also expect to receive another package describing in detail Mentor’s MemoryGel Post-Approval Study (PAS), which is scheduled to begin within 90 days post-approval.

We thank you for your loyalty and support during these last fourteen years as we worked to bring MemoryGel implants back to the market, and look forward to helping you smoothly integrate this new option into your practice.

Please contact your local sales representative if you have questions about any portion of this introductory package or your ongoing responsibilities.

Sincerely,



Kathleen M. Beauchamp

Vice President of Sales & Marketing  
Mentor Corporation

## IMPORTANT ADJUNCT STUDY INFORMATION

Dear Adjunct Study Investigator:

Mentor has received FDA approval for its Moderate Profile, Moderate Plus Profile, and High Profile Smooth and Textured Surface Round MemoryGel™ Breast Implants, which requires us to communicate very important changes to the Adjunct Study.

On the next page you will find a letter describing new information and obligations concerning the Adjunct Study which you should share with all study personnel. Within the next few days you will also receive an additional packet with a letter template for you to provide to your local IRB (if a local IRB was required for your participation in the Adjunct Study) along with a sample patient letter that should be reviewed and approved by the local IRB. Mentor will send a letter to the national IRB on your behalf reflecting the same information.

At this time there is no need to return any MemoryGel implant inventory to Mentor, as it may be used for approved indications after you have completed the Device Access Education training program and fully understand the new device registration requirements.

Please be advised that the product labeling has changed, and the new labeling can be found at [www.MemoryGel.com](http://www.MemoryGel.com). The “Important New Labeling Information and Material” letter has been included in product with updated packaging.

***The new labeling is different from previous materials in prior MemoryGel implant studies, and therefore it is important that you review all new labeling in its entirety before you use existing MemoryGel implants or order new product. You must also ensure that patient brochures are read and fully understood by your patients, consistent with the process of Acknowledgment of Informed Decision found at the very end of the patient brochures.***

If you participate in the Administrative Fee Program (AFP) program associated with our Adjunct Study, Mentor will conduct a final reconciliation of your Adjunct Study inventory. As audits are successfully completed, and if you are eligible, you will receive your administrative fee for this reconciliation.

With regard to **Lumera™** and **Becker** implants, you may ***ONLY*** use these for 90-day post-approval for patients that have already begun the Adjunct Study enrollment process. On day 90 post-approval all remaining Lumera and Becker implant inventory must be returned to Mentor, as these products will not be available for commercial use. Mentor will work with you to perform a final reconciliation of these products during the 90-day post-approval transition timeframe.

If there are any questions with respect to the new status or your obligations as an Investigator in the Adjunct Study, please contact your Mentor Clinical Research Associate at 1-800-258-3494.

Sincerely,

Ed Ramirez  
Manager, Clinical Compliance  
Mentor Corporation

To: Adjunct Study Investigators

Re: Mentor Adjunct Study and FDA Approval of Mentor's PMA Application for Moderate Profile, Moderate Plus Profile, and High Profile Smooth and Textured Surface Round MemoryGel™ Breast Implants

Dear Doctor and Study Coordinator:

Today, FDA approved our premarket approval application (PMA) for our Moderate Profile, Moderate Plus Profile, and High Profile Smooth and Textured Surface round MemoryGel breast implants 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 an original 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 an original primary breast reconstruction surgery.

We are excited about this news, want to acknowledge your significant contribution in this achievement, and also explain what this means to you. This approval comes as a result of hard work both here at Mentor and on the part of investigators and site coordinators who have participated in the study. This approval would not have been possible without your commitment to the Mentor Adjunct Study, compliance with the protocol, and willingness to follow your patients for their protocol-required postoperative visits.

As a condition of PMA approval, enrollment in the Mentor Adjunct Study for all round MemoryGel implants has now ceased. However, it is extremely important to understand that under the terms of the Investigator Agreement, patients already enrolled in the Adjunct Study will need to continue to follow up with you throughout the 5-year duration of the study. Please make every effort to bring them back for their 1, 3, and 5-year follow-up visits, and continue to report all adverse events.

Another condition of PMA approval requires that you complete Mentor's Device Access Education (DAE) course. Completion of this course will allow you to have access to the approved MemoryGel breast implants. As a former participant in the Adjunct Study, you may access and order product immediately; however, you are still required to complete your DAE course within 90 days post-approval if you plan to continue to order or implant MemoryGel breast implants.

The new product labeling is available at [www.MemoryGel.com](http://www.MemoryGel.com). The "Important New Labeling Information and Material" letter has been included in product with updated packaging. This new labeling is different from previous materials in prior MemoryGel implant studies.

***It is therefore important that you review all new product labeling in its entirety before you use existing MemoryGel implants or order new product. You must also ensure that patient brochures are read and fully understood by your patients, consistent with the process of Acknowledgment of Informed Decision found at the very end of the patient brochures.***

With regard to **Lumera™** and **Becker** implants, you may **ONLY** use these for 90-day post-approval for patients that have already begun the Adjunct enrollment process. On day 90 post-approval all remaining Lumera and Becker implant inventory must be returned to Mentor, as these products will not be available for commercial use. Mentor will work with you to perform a final reconciliation of these products during the 90-day post-approval transition timeframe.

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

Please contact your Mentor Clinical Research Associate at 1-800-258-3494 if you have any questions.

Sincerely,

Ed Ramirez  
Manager, Clinical Compliance  
Mentor Corporation





