

## IMPORTANT MEMORY GEL™ IMPLANT INTRODUCTORY INFORMATION

RE: 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:

Today, FDA approved our premarket approval application (PMA) for our Moderate Profile, Moderate Plus Profile, and High Profile Smooth and Textured Surface round MemoryGel 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, and are confident that these newly approved products will make a significant contribution to your practice and your patients.

As a condition of PMA approval, and your use of these products, you will have certain responsibilities. This package of information explains those responsibilities to you. Specifically:

1. If you are an Adjunct study investigator, you have several important obligations concerning cessation of new enrollment; ongoing follow-up of enrolled patients; Becker and Lumera™ inventory reconciliation activities; notices to your patients; and notice to your IRB. These activities are all described in the following "Important Adjunct Study Information" letter.
2. All physicians using MemoryGel implants will be required to complete Mentor's on-line Device Access Education (DAE) course. Specific information about the DAE course can be found in the following "Important Training Information" letter.
  - For physicians who have participated in either the Adjunct Study or the Core Gel Study, you may access and order product immediately. However, you are required to complete your DAE course within 90 days post-approval if you plan to continue to order product. The new product 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 shipped with updated packaging. The labeling differs from previous materials in prior MemoryGel studies. It is therefore important to 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.

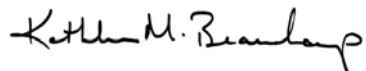
- For physicians who have not participated in a MemoryGel implant study, you are required to complete the DAE course prior to placing an order or accessing MemoryGel implants. Please refer to the “Device Access Education” letter included in this packet.
3. The FDA has determined that all physicians who 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