

IMPORTANT TRAINING INFORMATION

Mentor Device Access Education Course

Dear Dear Doctor:

As a condition to PMA approval, FDA is requiring that all physicians complete and document their training on Mentor MemoryGel™ Round Breast Implants. Accordingly, to comply with FDA requirements, you must complete our Device Access Education (DAE) Course as outlined below:

- If you are a former participant in the MemoryGel Implant Adjunct or Core Gel Study, you may access and order product immediately, but you must complete your DAE course within 90 days post-approval to continue to order MemoryGel implants. The new product labeling is available at www.MemoryGel.com. The “Important New Labeling Information and Material” has been included in product shipped with updated packaging. This document also references the new labeling. This new labeling is different from previous materials connected with 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. Also, you must assure that patient brochures are read and fully understood by your patients, consistent with the process of Acknowledgment of Informed Decision found at the end of the patient brochures.
- If you have not participated in the MemoryGel Adjunct or Core Gel study, you are required to complete the DAE course prior to placing an order or accessing MemoryGel implants.

The DAE course is available by accessing www.MemoryGel.com. The course contains three different modules: 1) Labeling Education, 2) Surgical Observation Video, and 3) Tracking Requirements. An important fourth element of this training is your acknowledgment of participation.

After reviewing all three modules of training in their entirety, we ask you to complete the Certificate of Participation, found at the end of the course. Please print the Certificate, sign it and return it to the fax number indicated on the Certificate. If you never participated in the MemoryGel Implant Adjunct or Core Gel Studies, you will not be able to order product until your Certificate is received and processed. Regardless of prior participation in these studies, your Certificate must be processed within 90 days of approval, for continued access to MemoryGel implants. Please retain a copy of the signed Certificate for your files.

If you experience any technical difficulties accessing the website or faxing the certificate, please call 1-888-457-1818. If you have any questions with respect to this training, we are available to assist you at 1-800-258-3494.

Sincerely,

Bernie Sturtevant
Director, Customer Services
Mentor Corporation