

Frequently Asked Questions

If you've enrolled in the Glow Study or are considering enrollment, you probably have questions. Mentor can help answer your questions about this clinical study and your participation. For more information on Mentor and the products included in this study, visit our website at BreastImplantsByMentor.com or ask your surgeon.



What is the purpose of this study?

This study will help Mentor collect supplemental 10 years of data on MemoryGel® and MemoryShape® Breast Implants.

Have the MENTOR® MemoryGel® and MemoryShape® Breast Implants already been tested?

These products have already been rigorously tested for safety and clinical performance. Our products are sold around the world because Mentor is committed to providing objective clinical information about breast implant safety so women can make an informed choice. To find out more information, please visit <https://www.breastimplantsbymentor.com/safety-information>

How does this study work?

This study will enroll participants in a Breast Implant group and a Control group. Participants in both groups will answer questions before and annually after surgery and these responses will be compared and analyzed.

What will I need to do if I participate?

This is a 10-year study so you should be able to commit to up to 10 years of follow-up after your surgery. Every year, you will fill out an online questionnaire. In order for the study to answer questions related to long-term outcome of patients with breast implants, it is important that all participants complete their questionnaire every year.

Are there any tests or procedures involved?

The only tests and procedures are those that are standard for pre-surgery and post-surgery, including the breast implant surgery itself, 2D photography, 3D imaging, and MRI or ultrasound when applicable.

How many people will be enrolled in this study?

More than 3000 women will participate in this study.

How often will I need to visit my physician?

There are no study-specific required visits after your surgery. After

your surgery, you will follow your surgeon's recommended care schedule for post-surgical care.

Who will pay for my participation and what will be paid for?

You will receive compensation for every annual study questionnaire that is completed and additional compensation if you complete all 10-years of study participation. You will also receive the Mentor Enhanced Warranty at no cost.

Who will oversee my medical care during the study?

Your surgeon will direct your care throughout the study.

What are my options if I have adverse events during this study?

You'll receive care from your physician, and you will also be covered under the Mentor Enhanced Warranty. This includes up to \$3500 in financial assistance coverage for 10 years for implant rupture treatment. It also includes implant replacement and up to \$3500 coverage for 10 years for capsular contracture (Grade III or IV), double capsule, and late seroma complications.

What happens if my physician retires before the study is completed?

You will still remain in the study and will still be able to complete your annual online questionnaires. The Mentor team will work with your physician to transfer you to another surgeon investigator.

What if I have an adverse event after the study is closed?

You can still report adverse events with your breast implants after the Glow Study has closed, and we encourage you to do so. The more data we collect, the more robust our results will be for other women to make informed choices. You'll be able to report adverse events directly to Mentor at 800-636-8678.

If you have additional questions, please contact your surgeon or learn more about clinical trials on the FDA website: <https://clinicaltrials.gov/ct2/about-studies/learn#considerations>.

