

PHYSICIAN/HOSPITAL/SURGERY CENTER DEVICE TRACKING REQUIREMENTS

[To be retained with your tracking files]

As an implanting Physician/Hospital/Surgery Center of Mentor's silicone gel-filled breast implants (MemoryGel™ implants) you are considered a "final distributor" under FDA device tracking authority and are subject to mandatory ongoing tracking requirements. As a "final distributor," you have collecting and reporting requirements, summarized below. These obligations, applicable to you, are required by law. If Mentor becomes aware that you have failed to comply with these requirements, Mentor is required to notify the FDA unless you take prompt steps to comply. Consequently, ongoing compliance is very important to both you and to Mentor.

Collecting/Reporting Requirements

- For each patient implanted with Mentor's MemoryGel Breast Implants, you must collect the information identified on the Device Tracking Form found in this information package and packaged with each device.
- A patient may refuse to release her name, social security number, or other identifying information. This refusal should be documented in the section of the Device Tracking Form requesting Patient Information (Section III) by checking the box or if patient refuses to give partial information this should be documented in the section "Explanation For Any Unavailable Information" (Section VI). All other non-patient specific information must still be provided.
- The product serial number is identified on the Patient Record labels contained in the implant box. Place the appropriate right and/or left implant serial numbers on the Device Tracking Form (Section I). If you cannot find the labels, manually write the number(s). They are found on the box label on the lower right side (as "SN").
- As a final distributor you have additional tracking and reporting requirements:
 1. Any device discarded or destroyed during surgery must be reported (Section II of the device tracking form)
 2. A patient's death must be reported (Section III of the device tracking form)
 3. If you replace a previously implanted device, the explanted device must be reported (Section VII of the device tracking form)
- Where tracking information is unable to be collected, there should be an explanation as to why that information is unable to be provided on the Device Tracking Form (Section VI).
- Following a report that the device has been explanted, returned, destroyed, or the patient has died, tracking is no longer required.
- FDA requires that physicians/hospital/surgery center provide the required device tracking information to Mentor's designated tracking entity promptly. Please fax the form within 24 hours following surgery to 866-216-4164.

If you have any questions at all about compliance, please contact Ed Ramirez, Manager, Clinical Compliance at 1-800-258-3494. Mentor is available to help you with these important requirements.