



The National Breast Implant Registry Patient Information Sheet

In collaboration with the U.S Food and Drug Administration (FDA) and breast implant device manufacturers, The Plastic Surgery Foundation (PSF) has developed a National Breast Implant Registry (NBIR) for the purpose of strengthening the post-marketing surveillance infrastructure for current and future breast implant devices in the United States. The NBIR is a database that collects information on breast implant procedures and devices. Collecting this information will allow the NBIR, plastic surgeons, and breast implant manufacturers to identify trends and other helpful safety information.

The information collected in the NBIR is used to improve the quality of care for all patients who undergo a breast implant procedure. Information from the NBIR can be analyzed to find trends in breast implant procedures, as well as identify potential complications that occur. Breast implant manufacturers can use the information collected in the NBIR to further study the long-term safety of their implants. The NBIR will also be used for Device Tracking purposes. Federal regulations require breast implant manufacturers to keep track of their silicone gel-filled breast implants that are on the market to identify who has what implant. This will directly benefit you in the event that new information related to your breast implant is obtained and can be conveyed to you.

The information from the NBIR could also be used for research purposes. The PSF can use the information collected by the NBIR to study trends related to all breast implant procedures. Physicians who participate in the NBIR can study the information entered about their practice to learn more about their patients and common procedures and complications. Physicians can also use the information in the NBIR to compare themselves to other plastic surgeons. Breast implant manufacturers can use the information collected in the NBIR to further study the long-term safety of their implants after they have been made available to patients.

Following your implant procedure, your information will be entered into the NBIR. If you decide that you do not wish to participate in the NBIR and/or do not want your name or contact information shared with the manufacturers for FDA-required Device Tracking purposes, please notify your physician as soon as possible. You will be able to discontinue your participation. Please note however, that if you do not agree to share your name or contact information with the manufacturers, they will not be able to contact you directly with updated information regarding your breast implants. In addition, your product warranty may not be activated, that is, go into effect, if you do not agree to share your name or contact information with the manufacturers.

Learn more at ThePSF.org/NBIR.



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