NATIONAL BREAST IMPLANT REGISTRY

Patient FAQ

This document explains how by participating in the National Breast Implant Registry (NBIR), your plastic surgeon aims to improve care for you and other patients who undergo a breast implant procedure.

What is the National Breast Implant Registry?

In collaboration with the U.S. Food and Drug Administration (FDA) and breast implant device manufacturers, The Plastic Surgery Foundation (PSF) has developed the National Breast Implant Registry (NBIR) for the purpose of strengthening national surveillance for 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 that can be used to improve the safety of breast implants for you and future patients.

How will this benefit me?

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.

Will the information from the NBIR be used for anything else?

The information from the NBIR could 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 theirpatients 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.

What kind of information will be collected in the NBIR?

The NBIR collects information about you and your procedure, including your contact information for future follow-up, information about your medical history, your breast implant operation and the implant itself, and any complications that may have occured from your breast implant operation.

THE PLASTIC SURGERY FOUNDATION

Plastic Surgery PSRN Registries Network

ThePSF.org/NBIR

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Will the NBIR collect any of my personal identifiable information?

Your personal identifiable information (PII) will be collected when your physician enters the information about your procedure into the NBIR. This information is "hidden" from the NBIR dataset so your PII will not be used for research purposes. This information is only collected for two reasons:

1. Instead of associating your case with your PII, your case will be automatically assigned an NBIR Registry ID number that is unique to you and your case. If a patient undergoes multiple breast implant procedures, each procedure will be separately entered into the NBIR. PII is collected and stored in the NBIR to identify when this happens. The NBIR database has the ability to recognize and link related cases together by assigning similar NBIR Registry ID numbers. This linkage will be done "behind the scenes", and will help researchers understand the reason patients undergo multiple breast implant procedures.
2. Manufacturers can use this information in the event that they need to contact you directly with updated information regarding your breast implants. However, if you decide you 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. Please note, your product warranty may not go into effect if you do not agree to share your name or contact information with the manufacturers.

Is the information about my case safe within the registry?

Yes. The NBIR database developer has taken all of the necessary precautions regarding data privacy to ensure the protection and safety of the all of the information entered into the NBIR.

Do I have to do anything to participate?

No. Your surgeon will be responsible for entering the information pertaining to your breast implant procedure into the NBIR.

Do I get anything for participating?

You will not be compensated for your participation in the NBIR. The information you contribute will provide insight into the safety of breast implants, and also help address any concerns raised by the FDA or other agencies.

Do I have to participate in the NBIR?

No. You have the opportunity to let your physician know that you do not want your information shared with the NBIR.

What if I no longer wish to participate in 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.

Where can I find more information on the NBIR?

Additional information regarding the NBIR can be found on the following website: ThePSF.org/NBIR. You may also contact research@plasticsurgery.org at any time with questions about the registry.