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Guidance

Symptoms sometimes referred to as Breast Implant Illness

Information for clinicians and patients.

Published 17 January 2020

From:
Medicines and Healthcare products Regulatory Agency (<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>)

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Symptoms sometimes referred to as Breast Implant Illness

Breast Implant Illness (BII) is a term sometimes used by people to describe a variety of health problems they associate with their breast implants

Reported symptoms

We have received reports from people with a variety of health problems which they say are related to their breast implants. The reports are not limited to a particular manufacturer or type of implant and include silicone and saline (salt water) filled implants, smooth or textured (rough) surface implants.

The reports often describe symptoms like “brain fog”, fatigue, anxiety and joint pain. These health problems are very concerning for those experiencing them.

There have also been reports of a serious medical condition in which the immune system mistakenly attacks the body (autoimmune disorders).

Some people have reported their symptoms improve once their breast implants were removed.

We, as with other regulators, continue to collect reports and information from a variety of sources, such as through our adverse incident reporting system and published research.

We encourage members of the public and healthcare professionals to report issues, even if suspected, with breast implants through the Yellow Card scheme (<https://yellowcard.mhra.gov.uk/>).

What we know

Currently we do not know if there is a link between breast implants and the reported health problems, as there is no single disease which could explain the symptoms some people are reporting to us or to their clinicians.

Very similar health problems were reported in the 1990s. A detailed review of the safety of smooth and textured silicone gel breast implants

(https://webarchive.nationalarchives.gov.uk/20110504132647tf_/http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice-A-F/Breastimplants/Siliconegelbreastimplants/IndependentReviewGroup-siliconegelbreastimplants/index.htm) was carried out by the Independent Review Group (IRG) set up by the Department of Health (now Department of Health and Social Care). This did not include saline filled breast implants which are not used frequently in the UK, however saline implants also have a silicone outer casing.

The IRG report published in 1998 found no evidence of a scientific relationship between silicone gel implants and any long-term illness affecting the whole body. It also found a lack of evidence of a link between silicone gel implants and any specific connective tissue disease, such as scleroderma, which causes hardening of the skin and some internal organs.

Worldwide, research into the safety of breast implants has continued over the last 30 years. Whilst there remains no definitive evidence or known scientific process demonstrating that breast implants cause these symptoms, we continue to look at research with our independent clinical experts to see if any new evidence comes to light which would increase our understanding of this issue.

We understand from the clinical community that there remains a need for these devices in certain clinical situations. The Association of Breast Surgeons (ABS), British Association of Aesthetic Plastic Surgeons (BAAPS) and the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) have recently published a joint statement (http://www.bapras.org.uk/docs/default-source/alci-guidance/25_11_final-joint-statement.pdf?sfvrsn=2), which also covers this topic.

We take a scientific evidence-based approach and if the conclusions reached about breast implants change in the light of this continuing evaluation, we will communicate further advice to patients and healthcare professionals.

Considering having a breast implant

For the majority of individuals breast implants are a personal choice but in a small number of people they may be suggested alongside other options, for example, to reconstruct the breast after cancer surgery.

Breast implants, as with any medical device, are associated with potential health risks. To make a fully informed choice, anyone considering breast implant surgery must be told by their implanting surgeon about the known short and long term risks, and be made aware there may be unknown risks. This

includes warning patients that some people have experienced a variety of symptoms which they associate with their breast implants.

More information about breast augmentation and breast reconstruction can be found at the following pages:

Breast enlargement (implants) (<https://www.nhs.uk/conditions/cosmetic-procedures/breast-enlargement/>)

Breast reconstruction (<https://www.nhs.uk/conditions/mastectomy/>)

MHRA's role and what are we doing

Patient safety is our highest priority and we always investigate where there are safety concerns raised about medical devices, including breast implants.

Our role is to identify medical device safety problems as early as possible (rather than 'recognise' conditions, diseases or illnesses) and adverse incident reports help us to do this. We also look at the scientific literature and consult academics and the clinical community. We work closely with an independent expert group, the Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG), as well as other regulators across the globe.

PRASEAG members represent breast surgery, toxicology, immunology, pathology and imaging. The group also includes a patient advocate and representatives from the ABS, BAAPS and BAPRAS.

To increase our understanding of breast implant safety, together with independent experts, we continue to pro-actively monitor reports and research from around the world. If any new evidence indicates a link between implants and the variety of symptoms reported, we will update this page and will update our advice as necessary.

Reporting suspected problems with breast implants

If anyone with a breast implants notices any lumps, swellings or distortions in their breasts, neck or armpits or develops any health problems they feel may be related to their breast implants they should see their GP or implant surgeon in the first instance.

We strongly encourage healthcare professionals and anyone experiencing any symptoms they believe to be associated with their breast implants to report these through the Yellow Card scheme (<https://yellowcard.mhra.gov.uk/>) and include the following information where possible:

- details of the implants, including manufacturer, model, batch number and surface texture. You may wish to ask your implanting surgeon for details of the manufacturer and model of your breast implants, so we have as much information as possible. However, if this is not possible, please be reassured your report will still be useful to us
- details of problems you have had with your implants and when the problems started. Tell us if your GP or surgeon has given you a diagnosis for these symptoms and if you are having any treatment, as well as any information following this treatment
- when you had the implants put in (the implantation date) and your age at the time
- whether you have had the implants removed or replaced? Please give dates of when this happened and details of any replacement implants
- whether the implants were put in for reconstructive or cosmetic reasons

- whether you have had previous breast implants or tissue expanders and for how long

Every report contributes to our knowledge about breast implants and their usage and helps us to develop suitable safety guidance and take appropriate action where necessary

For help reporting via the Yellow Card scheme, please watch this video on how to report a problem with a medical device – A Yellow Card guide for patients (<https://www.youtube.com/watch?v=U4btj0tJEP8&feature=youtu.be>).

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