

Breast Implant Illness - Frequently Asked Questions/Talking Points

Q: What is Breast Implant Illness (BII)?

A: *There are women with breast implants who self-identify and present with various systemic symptoms and believe that these are related to their breast implants. They refer to these symptoms as Breast Implant Illness (BII).*

Breast Implant Illness (BII) is a term used by women who have breast implants and who self-identify and describe a variety of symptoms including (but not limited to) fatigue, chest pain, hair loss, headaches, chills, photosensitivity, chronic pain, rash, body odor, anxiety, brain fog, sleep disturbance, depression, neurologic issues and hormonal issues that they feel are directly connected to their saline or silicone, textured or smooth breast implants.

The recent increase in patients reporting Breast Implant Illness (BII) symptoms appears to be related to social media. There is one Facebook group alone with more than 50,000 members, all of whom report Breast Implant Illness (BII) symptoms. This is not to say that social media is the cause of Breast Implant Illness (BII) however, it may account for the rapid increases in patient reporting. BII is not an official medical diagnosis.

Q: Is there a link between medical grade silicone implants and any disease?

A: *Silicone is an element that exists in nature as crystalline silica, which has been shown to activate the immune system in conditions such as systemic sclerosis which has been seen in stone masons. Silicone used in breast implants is different and to date has not been proven to cause any disease. This silicone does not exist in nature, it is created by hydroxylating silica to form polydimethylsiloxane. Medical grade silicone has had antioxidants, dyes, and plasticizers removed during processing.*

Q: Are there any tests that would indicate a connection between breast implants and symptoms that are being labelled Breast Implant Illness (BII)?

A: *There is no diagnostic testing specifically for Breast Implant Illness (BII). This is one of the current areas of focus for the Aesthetic Surgery Education and Research Foundation, the research arm of the American Society for Aesthetic Plastic Surgery. There are tests for autoimmune diseases that can be performed to evaluate for potential causes of a patient's symptoms. There are patients who have symptoms they attribute to Breast Implant Illness (BII) with positive immune testing and others with all laboratory tests which show no abnormalities.*

Q: Is there any scientific data showing causation between implants and these symptoms or any disease entity?

A: *In 1999, The Institute of Medicine Committee on the Safety of Silicone conducted an extensive review of the available literature and concluded there was no demonstrated clear link between silicone implants and any systemic illness. There have been studies of many different sizes and design to look at the safety of breast implants themselves. These have looked at specific autoimmune disorders and diseases. In aggregate, these studies show little to no links between breast implants and any disease. Studies of patients who have symptoms that they have related to their breast implants have not shown consistent laboratory abnormalities to*

define a distinct syndrome. To-date, there has been very little in the way of research into this entity that has been labelled Breast Implant Illness (BII) by women with breast implants.

Q: Does implant removal improve patient's symptoms or cure a patient who has a medically diagnosed disease entity like an autoimmune disease?

A: *Various studies show different degrees of improvement in patient symptoms after removal of their breast implants, some of which are temporary, and some showing permanent resolution of symptoms. There are no studies which specifically show which symptoms may or may not improve with implant removal with or without capsulectomy.*

There is no current definitive epidemiological evidence to support a direct link between breast implants and any specific disease process. However, this does not mean further research is not indicated. In rare and unusual disease processes, it can take years to come to a scientific conclusion. There are many factors that can affect the interaction between a patient and her breast implants. Further study is required to determine the best way to potentially screen patients prior to breast implant surgery and to determine which of the multitude of reported symptoms might improve with implant and capsule removal.

A lack of a direct, proven scientific link does not mean that the symptoms experienced by these patients are not real. Some patients have legitimate concerns about a potential link between breast implants and symptoms, so it deserves our attention and further scientific research to better determine what symptoms may improve with explanation of implants.

Q. *What are ASAPS and ASERF doing to better understand this group of systemic symptoms being called Breast Implant Illness (BII)?*

A. *Because there are many women that self-identify as having Breast Implant Illness (BII), we are listening. ASAPS and ASERF are developing a new scientific study to examine this entity. We are also providing our members with a questionnaire to use to collect a record of complaints from patients with implants, as well as one to utilize for post-explantation. We cannot yet define BII and therefore cannot say with any certainty that it exists, because we do not have any tests we can run to prove or disprove its existence. However, we can listen to and partner with our patients to determine what is the best course of action to address their complaints, be it explantation or otherwise.*

Q: What should a physician do when a patient complains of Breast Implant Illness (BII) symptoms?

A: *Do not ignore your patient's concerns. Their symptoms are real and whether or not they can or cannot be attributed to their implants isn't relevant since there is simply no existing way to prove nor disprove causation or association.*

Options can include: *further medical work up with or without the consultation of a rheumatologist, observation without medical work up, implant removal without capsulectomy, exchange with or without capsulectomy, removal with total capsulectomy, or removal with en bloc capsulectomy.*

Patients who present with concerns of Breast Implant Illness (BII) have real symptoms that often cannot be categorized into any specific know disease entity. This does not mean their symptoms are not real and they deserve a full evaluation. The various options need to be

discussed and hopefully, with further research, we may be able to determine which patients may see symptom improvement or resolution with removal of their implants and which may not see any change.

Q: What is the risk of developing Breast Implant Illness (BII)?

A: *As there is no definitive link between the often subjective and divergent list of symptoms, and no means for testing, there is no 'known' risk. Many of the symptoms described by breast implant patients are experienced by the general public on a regular basis with or without implants. That isn't to write-off a potential connection, but no connection has been established to-date.*

Patients should however be informed of the risks that can be associated with breast implants, including (but not limited to) BIA-ALCL, a rare spectrum of disorders that can range from a benign accumulation of fluids around the breast (seroma) to an extremely rare lymphoma. They should know that BIA-ALCL is not a cancer of the breast tissue itself and that when caught early, it is readily curable. If the disease is advanced, chemotherapy or radiation may be required.

Q: If after the discussion of risks and the possibility of no improvement of symptoms post-explantation is discussed with a patient, what should be done if the patient demands an "en bloc" or "total" capsulectomy with their explantation?

A: *There are many medical inaccuracies perpetuated by the internet. BII patients tend to believe that a total capsulectomy is necessary to remove all causative agents and they prefer it en bloc, oftentimes without having a full understanding of what size incision is necessary for en bloc. Rather than react, first discuss the reasons you would perform a total capsulectomy with any patient. Not all plastic surgeons routinely perform a capsulectomy with explant, but some do. If you wish to perform capsulectomy on a patient, it is important to explain that it is not always possible to remove all of the capsule. Sometimes a portion of the capsule must be left behind or is disintegrated with the use of electrocautery to prevent significant damage to muscle, rib or lung. Explain what size incision is necessary for an en bloc (as many may not be aware of how large an incision may be necessary). If they had an axillary approach or periareolar approach for breast implant placement, it must be explained to them that they cannot have the procedure done through those incisions. It is recommended to reinforce that there are increased surgical risks associated with en bloc capsulectomy which requires a complete dissection of all the tissues surrounding the breast implant and, that we do not have enough collective data to guarantee any improvement in their symptoms they have labelled Breast Implant Illness (BII).*