

WHERE CAN I GET MORE INFORMATION?

HERE ARE SOME RELIABLE RESOURCES FOR IMPLANT INFORMATION:

Health Canada, Canada
<https://www.canada.ca/en/health-canada/services/drugs-medical-devices/breast-implants.html>

Food and Drug Administration (FDA), United States of America
www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm259296.htm

Natrelle Website, Canada <https://www.natrelle.ca>

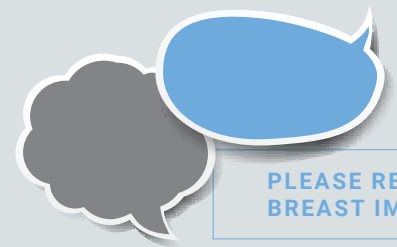
TO FIND A PLASTIC SURGEON WHO CAN ANSWER BREAST IMPLANT QUESTIONS:

Canadian Society of Plastic Surgeons (CSPS) <http://plasticsurgery.ca>

Canadian Society for Aesthetic Plastic Surgery (CSAPS) <https://csaps.ca>

International Society of Aesthetic Plastic Surgery (ISAPS)
isaps.org/procedures/breasts/breast-augmentation/

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Patient safety is the number one priority for Allergan.



PLEASE REMEMBER THAT YOUR SURGEON IS YOUR PARTNER THROUGHOUT YOUR BREAST IMPLANT JOURNEY. YOU SHOULD DISCUSS ANY CONCERNS WITH THEM.^{7,10,23}

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BA-PATIENT-INFO-COMPLICATIONS-IMPLANTS - 18 E

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IT'S YOUR BODY

AND YOU DESERVE ALL THE FACTS ABOUT GETTING BREAST IMPLANTS.

The following information answers many common questions possibly related to breast implants. Remember, your surgeon is your partner throughout your breast surgery. When you want to know more about these or about any other possible complications, ask your surgeon for additional information and the answers to your specific questions.

THE FOLLOWING COMPLICATIONS ARE DISCUSSED INSIDE:

1. Capsular contracture
2. Implant rupture
3. BIA-ALCL (Breast Implant-Associated Anaplastic Large Cell Lymphoma)

We've also included a list of online resources where you can find more information. As with any surgical procedure, breast implantation is not without risks. It is important that you get the facts and discuss what's best for you with your surgeon.



WHAT IS CAPSULAR CONTRACTURE?

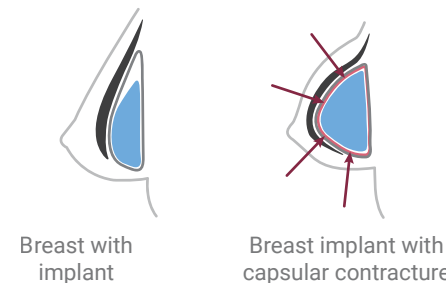
After surgery, your body begins to naturally surround the implant with a layer of scar tissue.¹ This tissue is called a “capsule” because it encapsulates (or surrounds) the implant.^{1,2} Sometimes, for a number of reasons, the capsule can tighten and squeeze the implant—this is called capsular contracture.^{1,2} It can cause the breast to feel hard, look misshaped, and can be painful.²

IS CAPSULAR CONTRACTURE TREATABLE?

Yes, it is treatable, although it may require additional surgery. Your surgeon can discuss this with you in more detail.²

WHAT ELSE SHOULD I KNOW ABOUT CAPSULAR CONTRACTURE?

It is one of the most common reasons for reoperation,³ and is also a risk factor for implant rupture.⁴ Your surgeon will



take steps to reduce your chance of developing capsular contracture.²

The severity of capsular contracture is graded using the four-grade Baker scale; Grade I capsular contracture is the least severe and Grade IV is the most severe.⁵ The warranty program offered by Allergan provides breast implant replacement in the event of significant capsular contracture (Baker Grade III/IV) within 10 years of surgery.

resonance imaging (MRI), and may be recommended as part of your post-surgery medical examinations.⁴

IS IMPLANT RUPTURE TREATABLE?

Yes, it is treatable. The removal of silicone gel-filled breast implants is recommended.⁴ Your doctor will diagnose if your implant has ruptured and determine if you should have it replaced or removed.⁴

SOME POSSIBLE CAUSES OF IMPLANT RUPTURE ARE:⁴

- Capsular contracture⁴
- Excessive force to the chest⁴
- Damage by surgical instruments⁴

ABOUT BIA-ALCL

(Breast Implant-Associated Anaplastic Large Cell Lymphoma)

WHAT IS BIA-ALCL?

BIA-ALCL is Breast Implant-Associated Anaplastic Large Cell Lymphoma, a T-cell lymphoma that can arise around breast implants placed for either reconstructive or cosmetic indications.⁶ Currently, the cause of BIA-ALCL is not clearly understood.⁶

WHAT CAUSES BIA-ALCL?

International health regulatory agencies are proactively working with implant manufacturers to study BIA-ALCL.⁷⁻¹⁰ To date, no specific risk factors have been identified, however, implant texture, genetics and bacteria have been implicated and are undergoing further study.⁶

IS IT COMMON?

It is estimated that there are 35 million women worldwide who have breast implants.¹¹ The true incidence of BIA-ALCL is hard to estimate.¹² To date, the estimated incidence rates in scientific literature range from 0.03% to 0.003%, or 1 in 3,817 to 1 in 30,000.^{13-16*}

WHAT ARE THE SYMPTOMS?

BIA-ALCL is most commonly reported at an average of 8–10 years following implant placement.¹⁷ The first symptoms are usually a swelling of the breast— often caused by fluid building up around the implant.⁶ Other symptoms can include pain, lumps, and unevenness between breasts.⁶

THE LONGER IMPLANTS ARE IN PLACE,
THE HIGHER THE CHANCE OF IMPLANT RUPTURE.⁴

IS IT TREATABLE?

Yes. When diagnosed early by a surgical specialist, BIA-ALCL can be treated, often successfully.⁶ In most cases, BIA-ALCL can be treated by removing the breast implant and surrounding scar capsule, however, additional treatment may be necessary depending on the individual.⁶ In cases where the disease has spread throughout the body, rare cases of death have been reported.^{6,18}

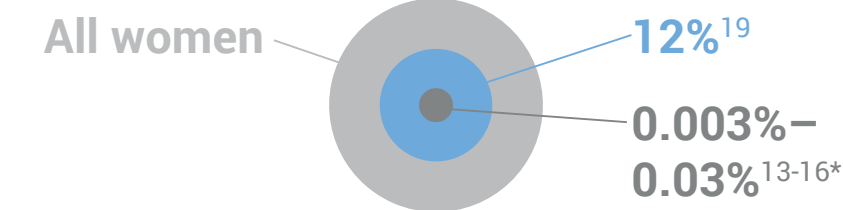
WHAT TYPES OF IMPLANTS ARE ASSOCIATED WITH BIA-ALCL?

BIA-ALCL has been associated with both saline and silicone implants, round and anatomic implants, all gel types, and all projections, as well as implants for both reconstructive and cosmetic purposes.⁶

WHAT ARE TEXTURED IMPLANTS AND HOW DO THEY AFFECT THE RISK OF DEVELOPING BIA-ALCL?

Breast implants have different surface textures, including smooth or textured. For cases reported to date, BIA-ALCL has been seen most often in patients with textured implants,⁶ however, the risk of developing BIA-ALCL with textured implants is low.¹⁵

PUTTING THE NUMBERS INTO PERSPECTIVE:



The average woman in the United States’ risk of developing breast cancer in her lifetime—that’s **1 in 8 women**.¹⁹

Although it has been difficult to quantify the incidence and prevalence of BIA-ALCL¹², the estimated incidence rates in scientific literature range from **1 in 3,817 to 1 in 30,000**.^{13-16*}

SHOULD I STILL CONSIDER A TEXTURED IMPLANT?

Surgeons have varying reasons for selecting a textured implant.²⁰ Some implant types, such as anatomically shaped implants, are only available with a textured surface.²⁰ Make sure to discuss the various implant options with your own surgeon since every woman is different and has different needs.

WHAT SHOULD MY SURGEON DO IF I ALREADY HAVE BREAST IMPLANTS?

If you have breast implants, there is no need to change your routine medical care and follow-up. Although not specific to BIA-ALCL, you should follow standard medical recommendations, including regular medical examinations as scheduled by your doctor. If you notice any changes, contact your health care provider promptly to schedule an appointment.^{7-10,21}

It makes good sense to monitor your breast implants. Perform regular breast self-examinations to make sure they feel normal and do not have any issues.^{7,9,22} Consult your healthcare provider if you notice swelling, pain, lumps or asymmetry after the surgery sites are fully healed.^{6-10,21}

WHAT IS ALLERGAN DOING ABOUT BIA-ALCL?

Patient safety is Allergan’s first priority. We are working closely with leading surgeons worldwide to increase awareness of the disease and the importance of early diagnosis. We will continue to work with the medical community to further the understanding of this disease.

Allergan also provides rare-events coverage, up to **\$5,000 USD**, for its products in cases of BIA-ALCL. Patients with Allergan implants are eligible for assistance with out-of-pocket surgical costs, not covered by insurance, including removal of the breast implant(s) and associated tissue.

* Publications referenced here include patient populations with breast implants and patients specifically with textured breast implants.

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