

Natrelle®

Your guide
to **breast**
reconstruction



Actual Natrelle® patient. Individual results may vary.

Every woman's *journey is different*

While your breast cancer diagnosis determines your journey, you have a choice in how you move forward with breast reconstruction.

In this brochure, you'll learn about your options and hear from real breast cancer patients with different diagnoses. Their stories may help shed some light on **breast reconstruction** during this difficult time.

While their journeys were different, in the end, one choice brought these women together: the choice to move forward with breast reconstruction surgery with implants.

CHOICE—it's truly a powerful thing.

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Bold words appearing within this brochure are defined in the glossary.



Mina

A mother of two young girls who prides herself on one of her biggest accomplishments yet—fighting breast cancer.

Actual Natrelle® patient.
Individual results may vary.

Your breast *surgical team*



BREAST SURGEON

Removes the cancer through a **lumpectomy** or **mastectomy** and/or other treatments.

If you're thinking about reconstruction, bring it up to your breast surgeon first.

It may impact how they perform your mastectomy.



YOU

You are at the centre of it all. Together, with both surgeons, you'll talk about your options and create a plan that's right for you.



PLASTIC SURGEON

Reconstructs your breasts using one of several methods. Reconstruction with breast implants is just one option. It's important to work with a plastic surgeon who specializes in the technique you want.

Post-mastectomy breast cancer reconstruction is covered by most provincial and territorial health plans

Making the right choice is a *team effort*

The decision to move forward with reconstruction can feel overwhelming. Leaning on friends, family, and other women on similar journeys can help you feel supported every step of the way.

You can also rely on your breast cancer care team. Involving your breast surgeon and plastic surgeon from the start will help you plan for the best results possible.

You have a **choice** in how you look

Talk to your plastic surgeon about the fullness you want—whether it is the same amount you had pre-mastectomy or something different.

Your final look depends on many factors, including how much breast tissue you have after your mastectomy. Your surgeon can help you choose the best option based on your needs, wants, unique body structure, and more.



**“Cancer has taken
so much from me,**

going through breast
reconstruction was a way to

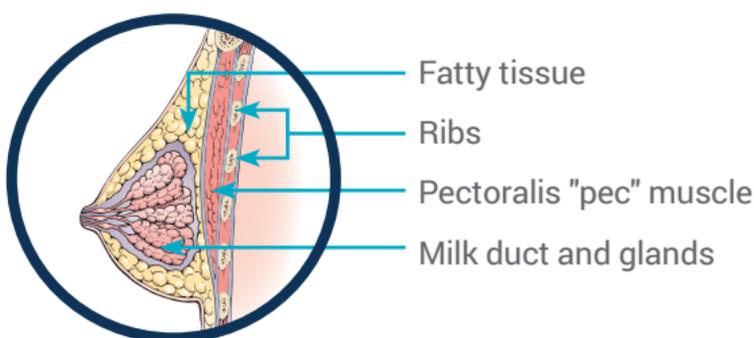
**take back control
over my life.”**

—Katherine

Actual Natrelle® patient.
Individual results may vary.

What gives the **breast its shape**

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. Beneath the breast is the chest muscle (**pectoralis** major "pec" muscle).



Breast cancer surgery could significantly change the shape of the breast, but this can depend on a number of factors. These factors include how much breast tissue is removed in a partial or complete mastectomy, how much skin is removed at the time of surgery, and how much tissue reaction or scarring there is in the remaining breast and skin in response to breast removal surgery, chemotherapy, or radiation therapy.¹

About breast **reconstruction**

Timing of breast reconstruction surgery: Immediate vs. delayed²

There are a number of factors that can influence the timing of when breast reconstruction may be carried out. Discuss the various options with your surgeon to decide which route is best for you.



Immediate reconstruction

- The breast reconstruction process starts at the **same time** as the breast cancer surgery
- Requires longer surgical time, but helps avoid the experience of having only one or no breasts



Delayed reconstruction

- The breast reconstruction process starts **after** the breast cancer surgery
- Allows for more time to think about your breast reconstruction options, but you may need to wait several weeks or months before being able to return to your natural body shape

Reconstruction *with implants:*

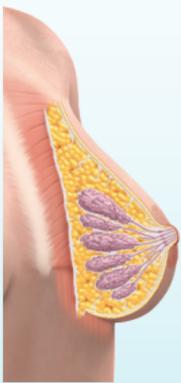
One-stage vs. two-stage breast reconstruction

One-stage reconstruction¹

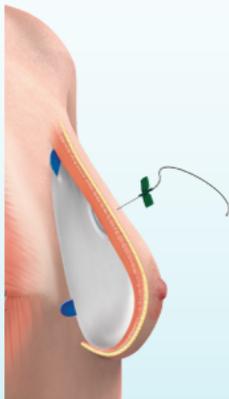
The procedure is carried out in one single operation, involving placement of a breast implant. Some patients are appropriate candidates for this type of surgery, and this should be discussed with your surgeon.

Two-stage reconstruction¹

Two-stage breast reconstruction is most common. It involves the insertion of a **tissue expander**, a temporary, inflatable silicone balloon-type device that is gradually filled with **saline** to stretch the skin and create the room needed for the permanent implant.¹¹ This process is similar to what occurs naturally to your abdominal skin during pregnancy.



*Before
mastectomy*



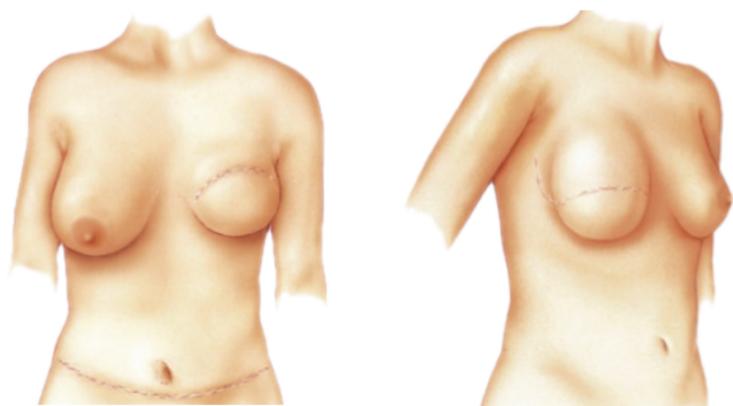
*Placed tissue
expander*



*Inflated tissue
expander*

Options for breast reconstruction surgery: With body tissue vs. with implants^{2,3}

Breast reconstruction can be carried out with the aid of a breast implant, by using your own tissue, or using a combination of the two. Talk to your surgeon about the options relevant to you.



With own tissue

(Autologous reconstruction)

Uses your own fat, skin, or muscle to make a breast

Section of tissue or flap may be taken from areas such as the abdomen or back:

- **TRAM flap (pedicle or free)** procedure uses fat, skin, and muscle from the abdomen
- **DIEP flap** procedure uses fat and skin from the abdomen without the muscle
- **Latissimus dorsi flap** uses skin and muscle from the upper back

With an implant

(Alloplastic reconstruction)

Uses a breast implant, placed under the muscle

Sometimes requires stretching of the skin with an inflatable tissue expander first, before placing the final implant

Combination of both

In some cases, both may be required to obtain desired results



“ I found the person that I always
wanted to be and

I couldn't be happier.”

—Tara

Actual Natrella® patient.
Individual results may vary.

Help find the *right fit for you*

Everyone's body is different. Even the smallest difference is important when it comes to selecting the right kind of breast implant. Before your surgeon recommends an implant, they will perform a series of comprehensive measurements and evaluate your skin and breast tissue characteristics in a process known as biodimensional planning. These measurements play a key role in determining what kind of implant fits your unique shape.^{4,5}

Your surgeon may consider:⁴

- The shape and size of your breasts
- Your skin and breast tissue characteristics
- The location of the **incision** and the implant
- Your goals and desires for surgery

Careful **pre-operative** planning is important because a breast implant that is too large for your tissue can result in excessive stretching of the skin and can contribute to the need for future corrective surgeries. It can also speed up the effects of gravity and result in earlier drooping or sagging, or may even be noticeable under your skin.^{4,5}

It is important to consider how both the size and shape of the breast implants fit your body. Choosing a breast implant involves so much more than choosing a cup size or volume. The size and shape of the breast implant should be as unique as your body type. The image below shows the same implant volume on 3 different body shapes:

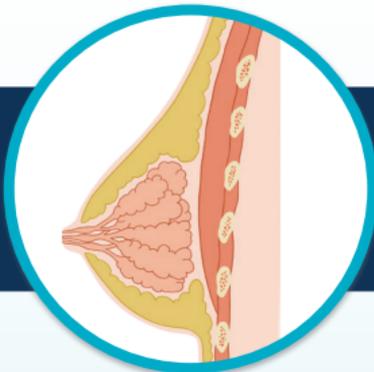


Reconstruction *incision sites*⁶

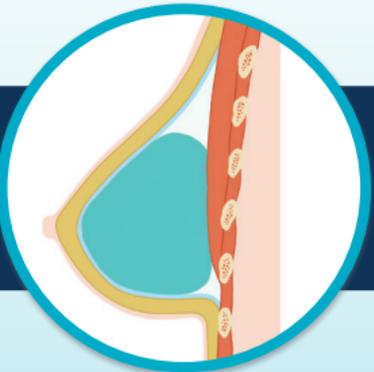
In reconstructive surgery the incision placement and length are decided by your surgeon, and largely influenced by the type of cancer surgery you have. Most implants in breast reconstruction use the mastectomy scar either immediately (during the mastectomy procedure) or after tissue expansion.

The placement of your breast implants⁷

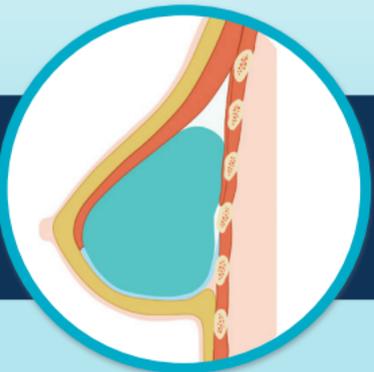
Your breast implant can be placed either wholly or partially under the pectoralis major "pec" muscle (**submuscular** or **dual plane**, respectively), or on top of the muscle and under the skin and any breast glands (**prepectoral**). Discuss with your surgeon the advantages and disadvantages of the implant placement selected for you.



Breast before mastectomy



Breast after **prepectoral** reconstruction



Breast after **submuscular** reconstruction

The **Natrelle[®] Inspira[®]** collection

The Natrelle[®] Inspira[®] Collection offers a variety of implants in different profiles and sizes. The right implant for you is a balance between the look you desire and what your breast measurements and tissue characteristics will allow.⁵ To help your surgeon restore your body to its natural shape, Natrelle[®] Inspira[®] offers a wide range of different implant options.⁸ Your plastic surgeon will discuss with you the implant size that will help you achieve the results that are right for you.

Only Natrelle[®] Inspira[®] is available in 5 projections, providing over 240 options to help you achieve your desired profile



Natrelle
INSPIRA[®] round gel

The next-
generation round



Width

Selecting the proper implant width is critical to help ensure your long-term satisfaction with your breast surgery. Natrelle[®] breast implants are available in different diameters, so your surgeon will be able to find the right match to fit the width of your breast, creating a more natural look.^{4,5}

Volume

Breast implants are measured by volume (cubic centimetres [cc] or grams), not cup size. Selecting the right volume for your body is key to achieving your desired look. Natrelle[®] offers a wide range of volumes, so you and your surgeon will be able to find the volume that you are looking for.^{4,5}

Projection

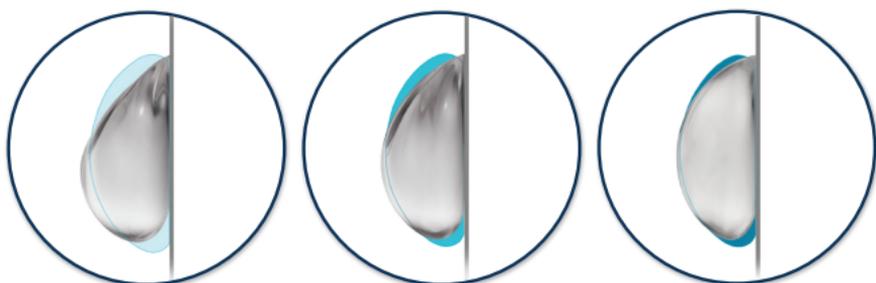
Projection refers to the distance your implants will extend forward from your chest wall. A higher projection can be a way to give the impression of a larger breast size.^{4,5} Only Natrelle[®] offers you 5 different projection options, all with optimal fill and volume, to meet your aesthetic goals.^{5,9}

Round breast implants

Breast cancer surgery can significantly change the shape of the breast, depending on how much breast tissue is removed, how much skin is removed at the time of surgery, and how much tissue reaction or scarring there is. Breast reconstruction surgery helps to restore your breast shape after a mastectomy, and uses round shaped implants that are filled with a cohesive gel to give the breast a “rounded” look.¹⁰

Gel

Only Natrelle® offers 3 different choices of silicone gels, which differ in firmness.⁴ Breast implants filled with firmer silicone gels maintain their shape better, keeping the fullness in the upper part (or upper pole) of the implant over time.⁵ You should consult with your surgeon on which of these gel fillers may best suit your needs.



TruForm® 1 Soft

The softest gel

TruForm® 2 Slightly firm

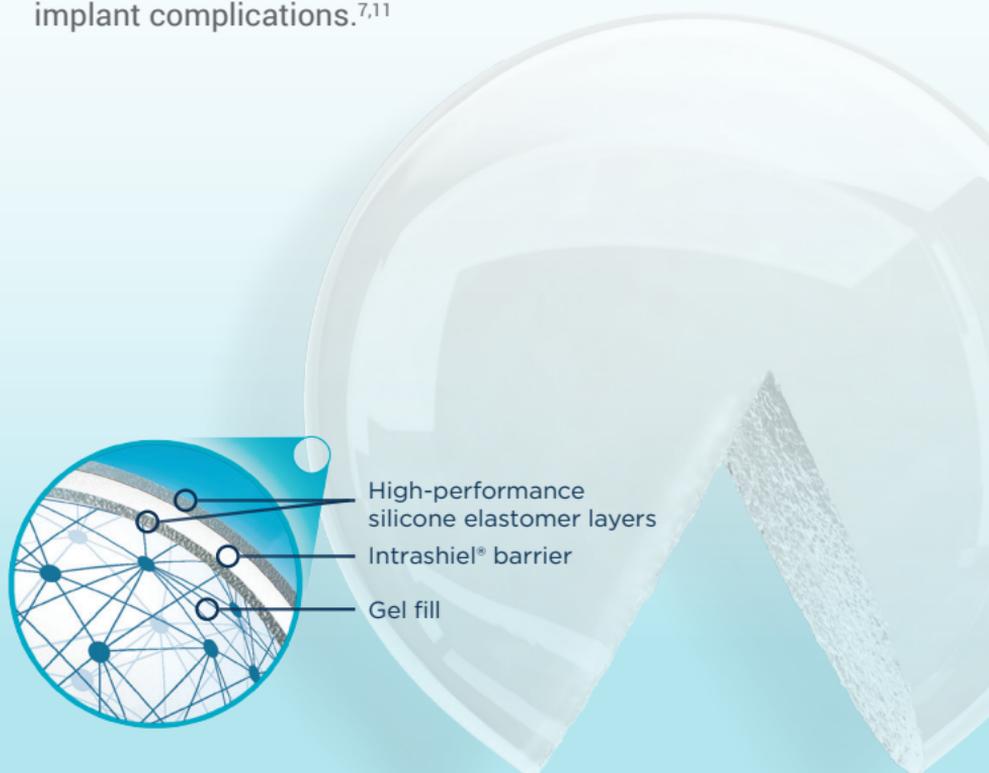
A slightly firmer gel, offering shape control with natural movement and feeling

TruForm® 3 Firm

The firmest gel for ultimate shape and control

Shell

Every Natrelle® Inspira® breast implant is surrounded by a state-of-the-art breast implant shell that is designed to keep the gel inside. This may reduce the risk of some breast implant complications.^{7,11}



Kayla

A brave 26-year-old with a family history of breast cancer who tested positive for a BRCA2 gene mutation and chose a double mastectomy and breast reconstruction.



Actual Natrelle® patient.
Individual results may vary.



With recent advancements in the development of breast reconstruction technology, your plastic surgeon now has more ways to create a look that's right for you.

The two-stage *reconstruction steps*

Once there is enough space in the breast, a second surgery will replace the tissue expander with a breast implant.

Before mastectomy



Stage 1: Tissue expanders are inserted and inflated



Natrelle® tissue expander

Stage 2: Tissue expanders are replaced with implants

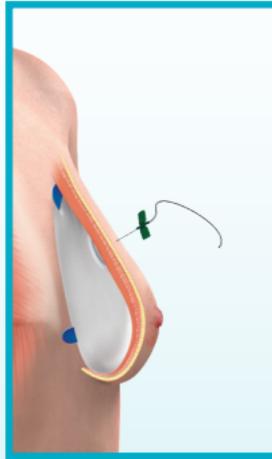


Natrelle® Inspira® Style SCLP-250 breast implant

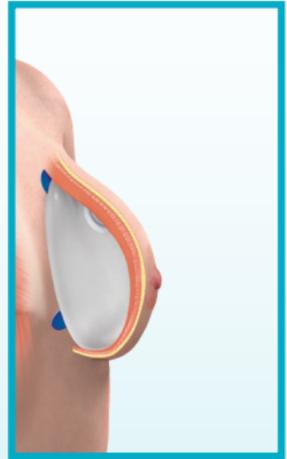
Photos provided by Dr. Allen Gabriel.
Individual results may vary.



Before mastectomy



Inflated tissue expander



Placed breast implant

Natrelle® 133S tissue expanders

The Natrelle® 133S tissue expanders are available in a wide range of options that are made to match the Natrelle® Inspira® round implants in both their width and projection. The Natrelle® 133S tissue expanders can be used in two-stage breast reconstruction to help prepare the tissue for an implant.^{12,13}



Pre- vs. post-reconstruction: **Real Natrelle® patients**

Reconstruction with Full Profile TruForm® 2 SoftTouch Implants



Natrelle® Inspira® Style SSF-520

Photos provided by Dr. Maurice Nahabedian. Individual results may vary.

Prepectoral Reconstruction with Full Profile TruForm® 3 Cohesive Implants and Fat Transfer



Natrelle® Inspira® Style SCF-415

Photos provided by Dr. Allen Gabriel. Individual results may vary.

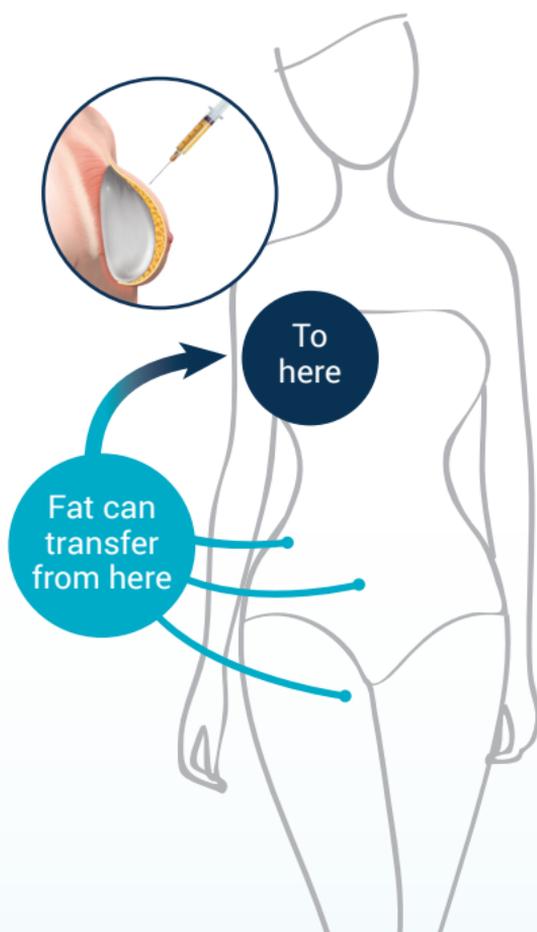


Natrelle® Inspira® Style SCF-650

Photos provided by Dr. Ritu Chopra. Individual results may vary.

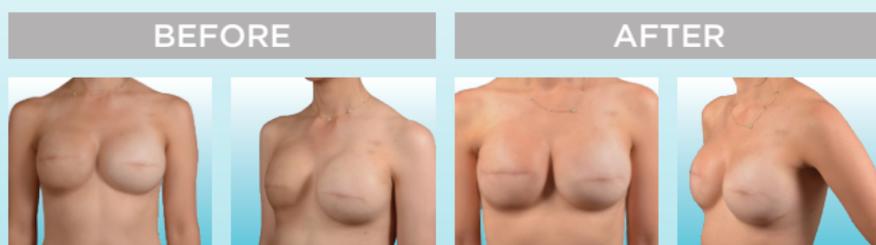
Enhancing your fullness

Fat transfer can help give you more fullness than an implant can sometimes provide.



Your plastic surgeon may suggest a fat transfer as part of your breast implant reconstruction.

Fat transfer allows your plastic surgeon to transfer your own fat from one area of your body to another. Adding fat to reconstructed areas, such as your breasts, can fill in contour irregularities or slightly increase size.



Breast reconstruction

Natrelle Inspira® Style SCF-520 (right)
Natrelle Inspira® Style SCF-485 (left)

Fat transfer added

Photos provided by Dr. Jacob Unger.
Individual results may vary.

Ask *the right questions*

Asking your surgeon the right questions and sharing any concerns you may have are important steps in getting the individual results that are right for you, and helping return your body to its natural shape. Please consider the following important questions for discussion at your next consultation:

What breast reconstruction options do I have?

What should I expect to happen the day of the surgery and how long before reconstruction is complete?

What are the risks and/or possible complications with implant-based breast reconstruction?

How should I prepare for the surgery recovery?

How much time is needed for the recovery process and when can I resume my regular daily activities?

What happens if the cancer returns or develops in the other breast?

What to expect *during your recovery*

Your experiences during recovery are directly affected by what happens during your surgery, for example, you may or may not have a surgical **drain**, which can be used to help minimize the collection of fluids during recovery. Shorter recovery times are now more common, thanks to advances in surgical techniques. During the immediate healing process (up to 3 months), it is generally recommended that you wear a **post-operative** surgical bra or breast binder to help stabilize the implants. Additionally, you will be required to refrain from vigorous exercise or other activities.¹⁴ For more information on what you can expect during and after your surgery, speak with your surgeon.

Post-operative *checklist*

Review this checklist with your surgeon to ensure you have received all your required information after your surgery.



Device identification card(s)

Supplied to you following surgery.



Device tracking form

Completed and returned by your surgeon's office to Allergan, if applicable



Post-operative care

Information for your specific post-operative care provided by your surgeon's office

Frequently asked **questions**

Are silicone implants safe to use?

Silicone is used safely in many medical devices and products, including pacemakers and heart valves, artificial joints, medical tubing, as well as everyday household items like baking pans, detergents, and fabrics.^{15,16} Silicone gel-filled breast implants are arguably the most studied medical devices in the world—there have been decades of research evaluating the safety and effectiveness of silicone implants.¹⁶ Silicone implants have been used extensively throughout the world, and are thought to look and feel natural.¹⁷

What are the potential complications with silicone implants?

Rupture

Breast implants are not lifetime devices.⁴ Breast implants can **rupture** when the shell develops a tear or hole. Ruptures are more likely to occur the longer the implant is implanted. If your surgeon determines you have signs of a rupture, you should discuss having the implant and any gel removed, with or without replacement of the implant.¹⁸

Capsular contracture

The scar tissue (**capsule**) that normally forms around the implant may tighten and squeeze the implant, making your breast feel firmer and sometimes painful. This is called **capsular contracture**.¹⁹ Capsular contracture occurs more commonly in **revision reconstruction** than in **primary reconstruction**.²⁰

Anaplastic large cell lymphoma (ALCL)

Anaplastic large cell lymphoma (ALCL) is a type of cancer that begins in the cells of the immune system.²¹ It can occur in children and adults, including women with or without breast implants. Over the last two decades, there have been reports of ALCL occurring in women with breast implants. This has led the medical community to recognize a new and different type of ALCL referred to as Breast Implant-Associated ALCL, or BIA-ALCL for short.

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)

BIA-ALCL is not breast cancer—it is a type of non-Hodgkin’s lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases, it can spread throughout the body. In the cases that it has spread beyond the scar tissue and fluid near the implant, rare cases of death have been reported.²²

Health Canada recognizes a higher risk of BIA-ALCL with implants having a textured surface, especially those with a more highly textured surface as opposed to implants with a smoother surface.²²

Do breast implants increase the likelihood of breast cancer?

Reports in the medical literature indicate that patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer.⁷ Women with breast implants are still able to have accurate **mammograms**, though it may be more difficult. Women should ask to have their mammography exams performed and interpreted at centres experienced in the evaluation of women with breast implants. Other breast screening exams such as ultrasound and MRI can also be performed when necessary.

Can breast implants impact a mother’s ability to breastfeed?

Studies have shown that mothers with breast implants do not have higher levels of silicone concentration in their breast milk than women who do not have breast implants. Many women with breast implants have successfully breastfed their children. However, breast surgery of any kind has the potential to impact **lactation** ability. Your plastic surgeon will discuss your options for incision placement, implant position, and other factors that could affect future breastfeeding.⁷

How much does breast reconstruction cost?

In Canada, post-mastectomy breast cancer reconstruction is covered by most provincial and territorial health plans. However, breast implants are not lifetime devices and will need to be replaced.⁴ Speak with your surgeon to discuss the options available to you.

Use this section to record important dates and contact information related to ***your breast surgery***

Surgery date:

Surgery location:

Contact person at surgery location:

Contact phone number:

Post-operative appointment date:

Notes

Our long-standing
commitment to creating
a natural look and feel

#1

medical aesthetics company²³

40

years as a global leader in
breast aesthetics^{*9}

30+

years of worldwide experience
with Natrelle[®] tissue expanders⁷

~\$1.5 billion USD invested in global research
& development in 2016 across Allergan's entire
portfolio of products²⁴

Lisa

A nurse with an active lifestyle who beat an aggressive form of breast cancer not once, but twice.

Actual Natrelle® patient.
Individual results may vary.

An integrated team, comprehensive knowledge, and shared decision-making can help optimize satisfaction with your breast reconstruction

More **coverage** for peace of mind

Silicone-filled breast implants

The Natrelle® ConfidencePlus™ Warranty Program:

	Rupture	Capsular contracture (Baker grade III/IV)†	Late seroma‡	BIA-ALCL§
Complimentary product replacement*	Lifetime	10 years	10 years	Lifetime
Financial assistance†	Up to \$3,500 USD within 10 years			Up to \$7,500 USD
Enrolment fee	Automatic—there is no fee			

For any warranty claim initiated **on or after January 1, 2020**.

Saline-filled breast implants

The Natrelle® ConfidencePlus™ Warranty Program:

	Saline deflation	Capsular contracture (Baker grade III/IV)†	Late seroma‡	BIA-ALCL§
Complimentary product replacement*	Lifetime (Complimentary round silicone-gel implant upgrades upon request)	10 years	10 years	Lifetime
Financial assistance†	Up to \$1,200 USD within 10 years			Up to \$7,500 USD
Enrolment fee	Automatic—there is no fee			

For any warranty claim initiated **on or after January 1, 2020**.

The Natrelle® ConfidencePlus™ Premier Warranty Program (saline warranty upgrade):

When purchased within 45 days following implantation surgery, the Natrelle® ConfidencePlus™ Premier Warranty Program includes all the benefits of the ConfidencePlus™ Warranty Program, plus:

	Saline deflation
Financial assistance†	 Up to \$3,500 USD within 10 years
Enrolment fee	\$200 USD—must enrol within 45 days of implantation surgery

The Natrelle® ConfidencePlus™ warranty does not include coverage for elective or preventative removal of breast implants.

For complete Natrelle® ConfidencePlus™ Warranty Program details and restrictions, please visit [Natrelle.ca](https://www.natrelle.ca)

BIA-ALCL, breast implant-associated anaplastic large cell lymphoma.

* Free **contralateral** breast implant replacement at surgeon's request.

† For out-of-pocket expenses not covered by insurance; subject to review and approval by Allergan following submission of all required documentation.

‡ For cases diagnosed within 10 years of the original surgery date.

§ BIA-ALCL coverage applies to all Natrelle® breast implants.

Glossary

The defined words in this glossary are **bold** the first time they appear within this brochure.

Alloplastic: The use of an implant for breast reconstruction.

Anaplastic large cell lymphoma (ALCL): A type of lymphoma, which is a cancer that begins in the cells of the immune system and can also occur in the breasts. A variety of ALCLs may occur in women with or without breast implants. When associated with implants, ALCL is often referred to as breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). ALCL is not the same as primary breast cancer.

Autologous: The use of your own tissue (fat, skin, or muscle) for breast reconstruction.

BRCA: A gene associated with breast cancer. Specifically, mutations in the BRCA1 (breast cancer gene 1) and BRCA2 (breast cancer gene 2) increase a woman's risk of developing breast cancer.

Breast reconstruction: A surgical procedure to replace breast tissue that has been removed due to cancer or trauma, or that has failed to develop properly due to a severe breast abnormality.

Capsular contracture: A tightening of the tissue capsule surrounding an implant, resulting in firmness or hardening of the breast and squeezing of the implant if severe. Capsular contracture is classified by Baker grades, where grades III or IV are the most severe, and contracture often results in the need for additional surgery because of pain and possible abnormal appearance. Capsular contracture can be a risk for rupture.

Capsule: Scar tissue that forms around the breast implant.

cc: Cubic centimetre—the measurement used for breast volume.

Contralateral: Opposite side.

DIAP flap: A tissue section (flap) of fat and skin from the abdomen, without the muscle, used for autologous reconstruction.

Drain: Tubes placed at the site of implant(s) post-surgery in order to remove any excess fluid buildup.

Dual plane: Placement of breast implants partially underneath the chest muscles.

Incision: A cut made to the body tissue during surgery.

Lactation: The production and secretion of milk by glands in the breast.

Latissimus dorsi flap: A tissue section (flap) of skin and muscle from the upper back used for autologous reconstruction.

Lumpectomy: Surgery used to remove cancer or abnormal tissue from the breast.

Mammograms: A type of X-ray examination of the breast used to detect cancer.

Mastectomy: Partial or full removal of the breast tissue, which is done to remove cancer cells from the body.

One-stage reconstruction: Breast reconstruction procedure that is carried out in one operation that involves the placement of the breast implant.

Pectoralis: Major muscle of the chest; also known as “pec.”

Post-operative: After surgery.

Pre-operative: Before surgery.

Prepectoral: Placement of breast implants underneath and within the breast glands, but on top of the chest muscles.

Primary reconstruction: The first time a breast implant is placed for the purpose of breast reconstruction.

Revision reconstruction: The correction or improvement of primary reconstruction. For this brochure, it refers to the surgical removal and replacement of breast implants.

Rupture: A tear or hole in the implant shell. Saline implants will deflate when they rupture.

Saline: A liquid solution that is made up of water and a small amount of salt.

Seroma: A buildup of the watery portion of the blood in a tissue location.

Submuscular: Placement of breast implants wholly or partially underneath the chest muscles.

Tissue expander: A temporary, inflatable silicone balloon-type device that is gradually filled with saline (salt water solution) to stretch the skin and create the room needed for the permanent implant.

TRAM flap: A tissue (flap) of fat, skin, and muscle from the abdomen used for autologous reconstruction. For a pedicle TRAM flap, the tissue flap is left attached to the original blood supply and moved to the breast area through a tunnel under the skin. For a free TRAM flap, the tissue flap is removed completely and reattached to the blood supply in the breast area.

Two-stage reconstruction: Breast reconstruction procedure that is carried out in two separate operations that involves the placement of the breast implant after a skin expansion process.

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Talk to your plastic surgeon about your breast reconstruction options, including Natrelle®.

Breast reconstruction surgery is not without risks and complications. The decision whether or not to have surgery and which procedure is right for you should be discussed with a trained and certified plastic surgeon.

For the listing of risks and complications, please visit:
www.allergan.ca/en-ca/products/medical-devices.aspx

For more information, talk to your doctor.
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