Natrelle®

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Allergan™

BREAST IMPLANTS

Natrelle®

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WARNING

Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a type of non-Hodgkin's lymphoma that women with breast implants have a very small but increased risk of developing. Surgeons should discuss the risk of BIA-ALCL with their patients prior to implantation. Regular follow-up is recommended.
Additional information is provided in the Warnings section of this document.

DESCRIPTION

NATRELLE® gel-filled breast implants are designed for use in augmentation and reconstruction mammoplasty. All *NATRELLE*® implants are constructed of a silicone elastomer shell and are latex free.

- *NATRELLE*® gel-filled breast implants are pre-filled with cohesive silicone gel designed to simulate natural breast tissue.
- *NATRELLE*® breast implants contain no latex or natural rubber materials.

IMPLANT DESIGN FEATURES

- *NATRELLE*® breast implants are available in a smooth surface.
- The shell features a patented barrier coat between two layers of silicone elastomer to minimise gel diffusion

EACH PATIENT MUST BE INDIVIDUALLY EVALUATED FOR IMPLANT SURGERY BASED ON THE CLINICAL JUDGEMENT OF A QUALIFIED SURGEON.

INDICATIONS

- Unilateral or bilateral hypoplasia of the breast.
- Breast reconstruction in patients with adequate tissue covering following mastectomy or trauma.
- Asymmetry, ptosis, or aplasia of the breast.
- Replacement of implants for medical or cosmetic reasons.
- Congenital deformity of the breast.
- A patient deemed suitable for breast augmentation must be at least 18 years old (22 years old in Singapore).

CONTRAINDICATIONS

- Tissue covering determined inadequate or unsuitable by the surgeon.
- Active infection, local and systemic.
- Existing carcinoma of the breast without mastectomy and residual gross local tumour of the breast after mastectomy.
- Advanced fibrocystic disease considered to be pre-malignant without mastectomy.
- Use of drugs that might result in high surgical risk and/or significant postoperative complications, including drugs that would interfere with blood clotting.
- A patient that demonstrates or shows signs of psychological instability (i.e., an inappropriate attitude or motivation).
- Women who are currently pregnant or breast feeding

RELATIVE CONTRAINDICATIONS/PRECAUTIONS

- Ptotic breasts where nipple falls below the inframammary fold, without concurrent mastopexy.
- To varying degrees, radiation damage, ulceration, compromised vascularity, or history of compromised wound healing which may affect tissue covering suitability.
- Previous repeated contour correction failures.
- Patients about to undergo radiation therapy and/or chemotherapy as this may make the use of breast implants more difficult and increase the risk of complications.
- Physiological condition determined by the surgeon to pose unduly high risk of surgical and/or postoperative complications. To varying degrees, obesity, smoking, diabetes, autoimmune disease, coagulopathy, chronic lung or severe cardiovascular disease may affect patient suitability for surgical implantation.

INFORMATION THAT SHOULD BE PROVIDED TO THE PATIENT

All patients should be informed of all the potential benefits and risks (see WARNINGS below) associated with the procedure prior to surgery.

Expected benefits include facilitating emotional healing after cancer, eliminating external prostheses, regaining body symmetry, allowing freedom in clothing and physical activities, and improving sexual or interpersonal relationships.

Patients should be informed about the implant options available, the surgical procedure including implant placement and incision site options. As this surgery will most likely be carried out under a general anaesthetic patients should be made aware of the risks associated with anaesthesia. Patients should discuss with their surgeon any history which may indicate a contraindication (relative or absolute) to surgery. Post-surgery care should be discussed, including time for wound healing, the need for any drainage tubes, recuperation duration, and the need for regular follow-up after primary surgery. Patients should be advised to consult a physician or pharmacist before using topical medicines (e.g. steroids) in the breast area, and if any clinical examination or surgery in the breast area is planned the patient should inform the doctor or nurse of the presence of an implant. The surgeon should advise the patient to consult a physician should she suspect any complications. All patients should receive a patient information booklet provided by Allergan.

Once the patient has received all the information, she should take at least 30 days to think about the risks and benefits of having breast implants before making a final decision.

WARNINGS

The surgeon should advise the patient that management of the complications listed below may include additional surgery or explantation.

Breast implants have a limited lifetime and the implant may have to be removed or replaced, which may necessitate revision surgery. Various factors, including the type of implant inserted, the type of surgery, injury to the breast, and excessive repetitive compression of the implant, may impact the longevity of the implants. Details on the expected lifetime of the implants are presented in the Rupture section below. As many factors affect the lifetime of a device and are outside the control of the manufacturer, the life expectancy of the implant cannot be guaranteed. The surgeon should discuss the necessity of pre-screening mammography with each patient as appropriate for her age and medical history.

1. Rupture

Gel implants may rupture at any time and require replacement or revision surgery. As ruptures are most often clinically silent, a radiological assessment may be required to aid diagnosis.

Causes of rupture include:

- Damage by surgical instruments
- Other trauma during surgery, such as improper handling or manipulation.
- Capsular contracture, or abrasive calcifications in the fibrous capsule.
- Closed or external capsulotomy.
- Stressors such as trauma, intense physical activity, vigorous massage and/or manipulation.
- Excessive compression during mammographic imaging.
- Umbilical endoscopic-assisted approach; preliminary reports indicate that there may be a higher incidence of rupture with this approach.

Long term Allergan Post-Market Surveillance data over eighteen years on gel-filled

breast implants indicates a rupture rate between 0.519% - 0.670%. Allergan US clinical study data on gel-filled breast implants indicates a rupture rate between 7.7% -9.7% at 10 years.

2. Capsular Contracture

Formation of a fibrous tissue capsule around an implanted device is a normal physiological response. Fibrous capsular contracture remains a common complication following breast implant surgery and is one of the most common reasons for reoperation. The cause of capsular contracture is unknown, however it is most likely multifactorial and may be more common following infection, haematoma, and seroma. Contracture develops to varying degrees, unilaterally or bilaterally, and may occur within weeks to years after surgery.

Contracture of the fibrous capsular tissue surrounding the implant may cause a range of symptoms including firmness, discomfort, pain, distortion, palpability, and/or displacement. Severe cases are considered the most clinically significant, and may require surgical intervention. Capsular contracture may recur subsequent to corrective surgical procedures.

DO NOT treat capsular contracture by external compression or massage, which may result in implant damage, deflation, folds, and/or haematoma.

3. Infection

Infection around a breast implant may occur within days, weeks, or even years, after surgery. Signs of acute infection reported in association with implants include erythema, tenderness, fluid accumulation, pain, and fever.

Infection that is unresponsive to treatment may require implant removal. Very rarely, Toxic Shock Syndrome has been reported as a possible complication of breast implant surgery and may also be associated with other types of implant surgery.

4. Necrosis

Necrosis may inhibit wound healing and require surgical correction and/or explantation. Permanent scar deformity may occur as a result of necrosis.

Do not use microwave diathermy in patients with breast implants. Microwave diathermy has been reported to cause tissue necrosis, skin erosion, and implant extrusion.

5. Haematoma/Seroma

Haematoma/seroma may occur in the postoperative period inhibiting wound healing, or have delayed onset, either of which may require surgical correction and/or explantation.

6. Inflammatory Reaction

In case of an inflammatory reaction, the surgeon is advised to remove the device from the patient's body and to secure any evidence on the possible cause of the inflammatory reaction and treat the patient correspondingly. It is advised not to replace the implant until the inflammatory reaction has passed completely and its cause has been eliminated.

7. Extrusion

Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion of the implant. In case of an extrusion, the device should be regarded as contaminated and should be removed. It may be replaced with another device after the wound has sufficiently healed.

8. Wrinkling and Folds

Palpable, or even visible, wrinkles and folds may occur. Folds may result in thinning and erosion of adjacent tissue, and extrusion of the implant. Folds may also result in crease-fold failure and rupture of the implant. If wrinkling occurs, the device may be replaced with an implant with a different filler or shape.

9. Interference with Standard Mammography/Self-Examination

The patient should continue to perform regular breast examinations for cancer screening; however, this may be more difficult with an implant.

The patient should be informed by the physician about the possible interference of the implant on the self-examination of the breast.

Patients should be instructed to inform their radiologists of the presence of an implant. With breast implants, routine screening mammography will be more difficult as the implant may interfere with diagnostic imaging. Because the breast and implant are squeezed during mammography, an implant may rupture during the procedure. More x-ray views may be necessary for women with breast implants; therefore, a patient may receive more exposure to radiation. However, the benefit of mammography is likely to outweigh the risk of the additional x-rays. Ultrasound may be a useful adjunct to mammography. Breast tissue imaging may be improved by submuscular placement of the implant.

10. Pain

As expected following any invasive surgical procedure, pain of varying intensity and duration may occur following implantation. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. Unexplained pain must be promptly investigated.

11. Breast Feeding and Sensation

Sensation in the nipple and breast can increase or decrease after implant surgery is typically lost after complete mastectomy where the nipple itself is removed, and can be severely lessened by partial mastectomy. Breast implants may impact the ability to breast-feed, though there is no conclusive clinical study data to support this. The peri-areolar incision may be associated with a higher likelihood of breast- feeding difficulties than other incision sites. The risk of temporary or permanent changes in breast sensation resulting from breast surgery could interfere with the patient's ability to breast-feed.

12. Dissatisfaction with Cosmetic Results

Scar deformity, hypertrophic scarring, capsular contracture, asymmetry, displacement, incorrect size, unanticipated contour, and palpability may occur. In some cases, cosmetic concerns may also lead to medical concerns. Careful surgical planning and technique can minimise, but not preclude, the risk of such results. Preexisting asymmetry may not be entirely correctable. Revision surgery may be indicated to maintain patient satisfaction but carries additional considerations and risks. If the patient is dissatisfied with the cosmetic result, revision surgery may be indicated; the device can be replaced with another device of different height, width, projection, volume, shape or filling, or may be placed in a different position in order to achieve a cosmetic result which is more pleasing to the patient.

Re-positioning of the implant during subsequent procedures should be carefully evaluated by the medical team and care taken to avoid contamination of the implant. Use of excessive force during any subsequent procedure can contribute to localised weakening of the breast implant shell potentially leading to decreased device performance.

13. Ptosis

Ptosis occurs naturally in all breasts over time. In case of ptosis, a mastopexy may be performed and/or the device may be replaced by another product with a larger volume or greater projection.

14. Calcification

Calcification commonly occurs in mature breast tissue with or without implantation. Microcalcification after implantation typically occurs on or around the fibrous capsule in thin plaques or accumulations. Extensive microcalcification may cause breast hardness and discomfort and may necessitate surgical intervention.

15. Tissue Atrophy/Chest Wall Deformity

Pressure of a breast implant may cause tissue atrophy. In rare cases, chest wall deformity has also been reported in association with the use of breast implants.

16. Gel Diffusion

Minute quantities of silicone may diffuse through the elastomer envelope of gel-filled implants. The detection of small quantities of silicone in the periprosthetic capsule, axillary lymph nodes, and other distal regions in patients with apparently unruptured, conventional gel-filled implants has been reported in the medical literature. However, there has been only limited evidence in medical literature associating gel diffusion with local complications in breast implant patients. If significant gel diffusion occurs, the device should be checked for any possible leakage or flaws.

17. Deformation

The unique nature of the highly cohesive silicone implant may require a larger incision compared to the incision size required for other silicone-filled implants to avoid skin edge trauma, implant deformation or separation/disruption of the gel. Excessive force upon insertion of the implant may compromise the precisely defined shape of the device, potentially leading to an undesirable cosmetic outcome.

18. Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

Based on information reported to global regulatory agencies and found in medical literature, an association has been identified between breast implants and the development of anaplastic large cell lymphoma (ALCL), a type of non-Hodgkin's lymphoma. Women with breast implants may have a very small but increased risk of developing Breast Implant Associated ALCL (BIA-ALCL) in the fluid or scar capsule adjacent to the implant, with documented potential for local, regional and distant spread of the cancer with mortality reported in rare cases.

BIA-ALCL has been reported globally in patients with an implant history that includes Allergan's and other manufacturers' breast implants with various surface properties, styles, and shapes. Most of the cases in the literature reports describe a history of the use of textured implants.

You should consider the possibility of BIA-ALCL when you have a patient with late onset, persistent peri-implant seroma. In some cases, patients presented with capsular contracture or masses adjacent to the breast implant. When testing for BIA-ALCL, collect fresh seroma fluid and representative portions of the capsule, and send to a laboratory with appropriate expertise for pathology tests to rule out ALCL, including immunohistochemistry testing for CD30 and ALK (anaplastic lymphoma kinase). If your patient is diagnosed with peri-implant BIA-ALCL, develop an individualised treatment plan in coordination with a multi-disciplinary care team. Because of the small number of cases worldwide, there is no worldwide consensus on the treatment regimen for peri-implant BIA-ALCL. However, the National Comprehensive Cancer Network (NCCN) recommends surgical treatment that includes implant removal and capsulectomy ipsilaterally as well as contralaterally, where applicable (NCCN Clinical Practice Guidelines in Oncology, T-Cell Lymphomas. (Current version)

RESEARCH ON SILICONE IMPLANTS

A report published in 1998 by a US National Science Panel, appointed by Judge Sam Pointer, evaluated the scientific data on silicone breast implants in relation to connective tissue diseases and immunologic dysfunction. No association was found between silicone gel-filled implants and any of the definite connective tissue disorders (including Sjogren's Syndrome) or other autoimmune/rheumatic conditions. They found that women with silicone breast implants do not display a silicone-induced systemic abnormality in the types or functions of cells of the immune system.

In 1999, an independent review from a committee at the Institute of Medicine in the US reported that connective tissue disorders, cancer, neurological diseases or other systemic complaints or conditions are no more common in women with breast implants than in women without implants. They concluded that a review of the toxicology studies of silicones and other substances known to be in breast implants does not provide a basis for health concerns.

INSTRUCTIONS FOR USE

SURGICAL PROCEDURE

Allergan relies on the surgeon to know and follow the proper surgical procedures with *NATRELLE*® implants. The surgeon must carefully evaluate implant size and contour, incision placement, pocket dissection and implant placement criteria with respect to the patient's anatomy and desired physical outcome.

Planning & Preparation

- Planning should include clear delineation of aesthetic goals to ensure mutual understanding between surgeon and patient. The surgeon should observe current and accepted techniques to minimise the risk of adverse and potentially disfiguring outcomes.
- The size and shape of the device may be determined preoperatively by means of dimensional planning or intraoperatively with the help of temporary sizer devices.
- A pre-surgical plan should be in place prior to the procedure that includes size of implant, type of implant, incision site, and plane of placement (i.e., submuscular vs. subglandular), as well as assurance that there is adequate tissue coverage for the chosen implant.

Implant Size Selection

- Note that larger implants, subglandular placement, and an insufficient amount of skin/tissue available to cover the implant may cause the implant to be more palpable.
- Available tissue must provide adequate coverage of the implant.
- Carefully evaluate breast implant size and contour, incision placement, pocket dissection, and implant placement criteria with respect to the patient's anatomy and desired physical outcome.
- Select an implant consistent in size with the patient's chest wall dimensions, including base width measurements, bearing in mind the laxity of the tissue and the projection of the implant.

Implant Placement

- Note that the possible risks of submuscular placement may include longer surgery, longer recovery, greater postoperative pain, and increased difficulty when performing some reoperation procedures as compared to subglandular placement. The possible benefits of submuscular implant placement include: less palpable implants, less likelihood of capsular contracture, and easier interpretation of mammography images. Also, submuscular placement may be preferable if the patient has thin or weakened breast tissue.
- Note that subglandular placement may reduce surgery and recovery times, may result in less postsurgical pain, and may allow for easier access to the implant, if revision surgery is necessary. However, subglandular placement may result in more palpable implants, greater likelihood of capsular contracture, and increased difficulty in interpreting mammography images.
- Bear in mind the importance of limiting pocket dissection

Incision Site Selection

- Note that the use of a peri-areolar incision results in a surgical dissection of breast parenchyma that may be associated with an increased risk of breast feeding difficulties, as compared to the use of other incision sites. Additionally, a peri-areolar incision may carry an increased risk of infection and change in sensation in the nipple-areolar complex (NAC).
- Take special care during breast reconstruction procedures carried out via the mastectomy scar to ensure that adequate healthy tissue coverage is available and that the implant is properly sized and positioned based upon careful preoperative planning.
- The peri-umbilical approach has not been studied in Allergan clinical studies and should not be used due to potential damage to the implant shell during implantation.
- Be aware that the unique nature of the highly cohesive gel may require a larger incision compared to the incision size required for other silicone-filled implants to avoid skin edge trauma, gel fracture or implant deformation.

GENERAL DEVICE IMPLANTATION AND EXPLANTATION CONSIDERATIONS

- NOTE: Smoking may interfere with the healing process.
- *NATRELLE*® products are designed and tested for compatibility with sterile water and saline solution. Other substances, such as alcohol or other chemical agents have not been tested in combination with the *NATRELLE*® products.
- *NATRELLE*® products should not be exposed to extreme heat, cold or pressure.
- No excessive force should be used while implanting or removing an implant and, accordingly, the skin incision should be planned for a sufficient size.
- No sharp objects such as knives or needles should be used in direct vicinity of any *NATRELLE*® product
- Do not alter the implants or attempt to repair or insert a damaged device.
- Do not place more than one implant per breast pocket.
- Back-up implants must be available during the procedure.
- Any serious incident should be reported to Allergan

SINGLE USE

These products are intended for single use only.

DO NOT reuse explanted products.

RISKS ASSOCIATED WITH REUSE

NATRELLE® breast implants are not intended to be re-sterilised or re-used. The cleaning and autoclaving process can cause damage to the breast implants, which could lead to loss of structural integrity. Reuse of the device can cause risk of infection to the patient.

PRODUCT IDENTIFICATION

Product labels are supplied within the internal product packaging of each *NATRELLE*® implant. The product labels provide specific information which allows product identification.

Important: These labels must be attached to the patient and hospital/doctors' records to ensure product identification and device traceability.

STERILE PRODUCT

Each implant is sterilised by dry heat sterilisation and is supplied in a sealed, double primary package.

DO NOT use the product if the thermoform packages or seals have been damaged.

STORAGE CONDITIONS

Avoid prolonged exposure to extreme storage conditions. Store these devices at ambient room temperatures and at atmospheric pressure and in dry conditions away from direct sunlight.

HOW TO OPEN STERILE PRODUCT PACKAGE

Remove the implant from the package in an aseptic environment and using talc-free gloved hands.

DO NOT expose the implant to lint, talc, sponge, towel, skin oils or other surface contaminants.

1. A non-sterile team member peels open the outer package.
2. The surgeon/scrub nurse removes the inner package and places it into the sterile field.
3. Peel open the inner package.
4. Gently retrieve the implant.

Prior to use, keep the implant covered in the inner package, to prevent contact with airborne and surgical field particulate contaminants.

PRELIMINARY PRODUCT EXAMINATION

Prior to use, examine the implant for any evidence of damage or particulate contamination.

IMPLANT PLACEMENT

Ensure incision is sufficiently large, to facilitate insertion and avoid damage to the device. Inadequate pocket dissection increases the risk of rupture and implant malposition. DO NOT use excessive force during placement of gel-filled implants. Silicone gel may be permanently deformed due to over-manipulation, resulting in deformation of the shape.

INSTRUCTIONS AND PRECAUTIONS FOR REMOVAL

In case that removal of the product is necessary, the device should be removed from the patient without harming or breaking the outer shell of the product, if possible. If the outer shell of a silicone gel-filled implant is harmed or broken, all remnants of the silicone gel filling that might have exited the device must be removed from the patient's body mechanically or washed out. The wound and former implant pocket should then be thoroughly rinsed with physiological saline solution. All devices removed from a patient's body should be treated as potentially contaminated, either safely disposed of or processed, and returned to Allergan as per the instructions below.

METHOD FOR REMOVING RUPTURED GEL FROM THE SURGICAL POCKET

In the event of implant rupture, the following technique is useful for removal of the gel mass. Wearing double talc-free surgical gloves on one hand, use the index finger to penetrate the gel mass. With the other hand, exert pressure on the breast to facilitate manipulation of the gel mass into the double-gloved hand. Once the gel is in hand, pull the outer glove over the gel mass and remove. To remove any residual gel, blot the surgical pocket with gauze sponges. Avoid contact between surgical instruments and the gel. If contact occurs, use isopropyl alcohol to remove the gel from the instruments. Ruptured implants must be reported and returned to Allergan as per the instructions below.

RETURNED GOODS POLICY

Product returns and exchanges must be authorised through your Allergan representative.

Exchange value is based on time limitations. All package seals must be intact to be eligible for return or exchange. Returned products may be subject to a restocking charge. Certain products are non-returnable. For more information, please contact your Allergan representative.

REPORTING AND RETURN OF EXPLANTED DEVICES

Explanted devices associated with a complaint or injury must be reported and returned to your local Allergan representative with a Product Field Note (PFN). In order for the explanted product to be returned to the manufacturer it must first be decontaminated and a Decontamination Certificate completed and returned

with the explanted device within an explant return kit. Do not return device if the patient has HIV or hepatitis or is known or suspected to carry another infectious agent. Please notify your Allergan representative in these circumstances.

PRE-DISINFECTING INSTRUCTIONS:

Do not puncture the device.

DISINFECTING METHODS:

Autoclave:

- DO NOT use a pre-vacuum autoclave or ethylene oxide steriliser.
- Set autoclave on the "slow exhaust" or "liquid" setting.
- Autoclave by the following gravity displacement cycle: minimum of 70 minutes at 121°C, 1kg/cm^2 (250°F, 15 psi).
- Open door slowly once the cycle is completed and allow device to cool to room temperature before preparing for shipment.

Bleach (use only if autoclave is not available):

Note: Do not use alcohol, *Cidex*® (glutaraldehyde), formaldehyde or other solutions for disinfecting.

- Mix one part of household bleach (10% sodium hypochlorite) with 9 parts of water.
- Completely submerge the explanted device in the solution for 60-120 minutes.
- Rinse thoroughly with water and dry the device.

A Product Field Note, shipping instructions, and a decontamination certificate within an Allergan return kit is required prior to dispatch of each explanted device. These can be obtained by contacting your local Allergan office/local distributor.

PRODUCT REPLACEMENT POLICY

In the event of non-iatrogenic loss of breast implant shell integrity within ten years from the date of implantation, the device will be replaced with an identical or equivalent device. To receive a replacement device, a Product Field Note (PFN) must be completed and submitted to your Allergan representative. Explanted devices must be returned in accordance with section above "Reporting and Return of explanted devices". The product replacement policy does not cover surgical or other expenses related to rupture, deflation, cosmetic revision, capsular contracture, or other adverse events. Contact your local Allergan representation for specific warranty details for your region

LIMITED WARRANTY, LIMITATION OF LIABILITY, AND DISCLAIMER OF OTHER WARRANTIES

Allergan warrants that reasonable care was used in the manufacture and production of this product. Allergan has no control over the conditions of use, patient selection, surgical procedure, post-surgical stresses, or handling of the device after it leaves our possession. Allergan does not warrant either a good effect or against an ill effect following its use. Allergan shall not be responsible for any incidental or consequential loss, damage or expenses directly or indirectly arising from use of this product. Allergan's sole responsibility in the event that Allergan determines the product was defective when shipped by Allergan, shall be replacement of the product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law, or otherwise, including, however not limited to, any implied warranties of merchantability or fitness for use.

INFORMED CONSENT

An Informed Consent Form is provided (see back of book). Please ensure that the patient receives the information from the section "INFORMATION THAT SHOULD BE PROVIDED TO THE PATIENT" and understands the information provided. The patient must realise that the surgical and post-surgical risks associated with implants cannot be completely predicted, even with the best medical manufacturing, technology and surgical care, and accept these conditions and limitations. Patients must fully inform their physician of their medical history, including any and all conditions that would contraindicate implant surgery. Failure to inform their physician could result in significant surgical and post-surgical complications. The patient must decide herself on whether the expected benefits outweigh the said risks. If the patient decides that the expected benefits of the proposed implant surgery outweigh the risks, then she must take full responsibility for her choice to proceed with implant surgery. The two-part form located at the back of this book should be completed and signed once the patient has decided to proceed with implant surgery. This form allows both the patient and the surgeon to retain copies for their records.

ID CARD

As part of device tracking, Allergan is providing a patient ID Card. The information on the inside of this card (when folded) is specific to the device(s) the patient received (patients should keep this card for their records and carry it at all times to facilitate medical care in case of emergency). If a device is replaced, another card will be provided for the new device. The ID Card is located at the back of this book.

Instructions for the Surgeon:

Place one label from each product in the appropriate space on the ID Card (L or R). These labels can be found attached to the bottom of the main inner label on top of the inner product packaging.

Fill in all the remaining sections. Give this entire document to the patient for her records. See "Graphical Symbols" for explanation of symbols.

GRAPHICAL SYMBOLS

STYLE	DEVICE STYLE
GF	GEL FILL
L	CHECK FOR LEFT BREAST IMPLANTATION
R	CHECK FOR RIGHT BREAST IMPLANTATION
SN	SERIAL NUMBER
LOT	LOT NUMBER
REF	CATALOGUE NUMBER
ID CARD	IDENTITY CARD
STERILE YYYY-MM-DD	STERILE, DRY HEAT STERILISED, DATE OF STERILISATION, YEAR-MONTH-DAY
	SINGLE USE ONLY - DO NOT REUSE
YYYY-MM-DD	USE BY, YEAR-MONTH-DAY
	ATTENTION, SEE INSTRUCTIONS FOR USE
	ROUND DIAMETER OF IMPLANT
	IMPLANT PROJECTION
	MANUFACTURER
	DO NOT RE-STERILIZE
	DO NOT USE IF PACKAGE IS DAMAGED
	STORE AWAY FROM SUNLIGHT
	KEEP DRY
105 kPa 98.2 kPa	KEEP AT ATMOSPHERIC PRESSURE (98.2 TO 105 KPA)

Natrelle® Informed Consent Form

- I confirm that I have read the *Natrelle*® patient information brochure
- I confirm that I have had ample opportunity to discuss my concerns and options with my surgeon
- I confirm that my surgeon has given me time to consider *Natrelle*® breast implant surgery
- I fully understand the effects and risks associated with having *Natrelle*® breast implant surgery
- I consent to undergoing *Natrelle*® breast implant surgery as discussed with my surgeon.

SIGNED BY: **DATE:**

Print or type patient name:

SIGNED BY: **DATE:**

Print or type witness name:

Surgeon Copy

Natrelle® Informed Consent Form

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- I confirm that I have had ample opportunity to discuss my concerns and options with my surgeon
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- I fully understand the effects and risks associated with having *Natrelle*® breast implant surgery
- I consent to undergoing *Natrelle*® breast implant surgery as discussed with my surgeon.

SIGNED BY: **DATE:**

Print or type patient name:

SIGNED BY: **DATE:**

Print or type witness name:

Patient Copy

Please use black ball-point pen when filling out this card.

Surgeon:

Clinic:

Address:

Natrelle

☎ :

Date of Implantation:

_____ / _____ / _____

ID Card

Gel-Filled Breast Implant:

Name:

Natrelle

Allergan™

ALLERGAN, Marlow International, Parkway, Marlow,
Bucks, SL7 1YL, United Kingdom
https://www.allergan.com.au/en-au/products

Natrelle

Place Patient ID Sticker Here

Style

(R)

Natrelle

Place Patient ID Sticker Here

Style

(L)