Preoperative BREAST AUGMENTATION surgery planning with a full line of *Natrelle*® gummy implants

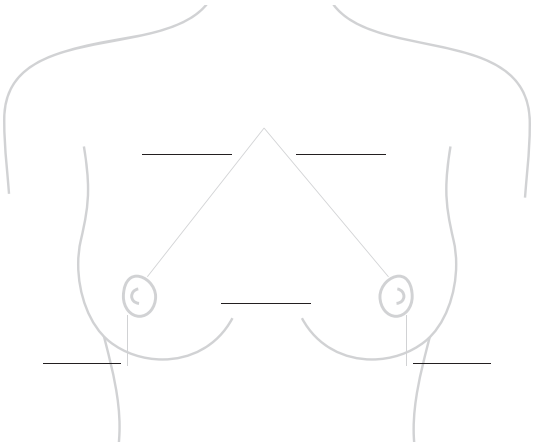
PATIENT INFORMATION

Patient name

Age Ht Wt

Surgeon name Surgery date

Surgery location/facility



BREAST PARAMETERS

	RIGHT BREAST	LEFT BREAST
Base width	_____ cm	_____ cm
Nipple to inframammary fold distance	_____ cm	_____ cm
Nipple to new inframammary fold distance	_____ cm	_____ cm
Intermammary distance	_____ cm	
Sternal notch to nipple distance	_____ cm	_____ cm
Internipple distance	_____ cm	
Nipple to midline distance	_____ cm	_____ cm
Areolar diameter	_____ cm	_____ cm

PATIENT EVALUATION

Larger breast ☐ Right ☐ Left Est vol diff ____ cc

Nipple level discrepancy _____ cm

IMF level discrepancy _____ cm

Envelope compliance ☐ Normal ☐ Loose ☐ Tight

Tissue coverage ☐ Thin ☐ Adequate ☐ Moderate

Upper pole pinch test Right _____ cm Left _____ cm

Other

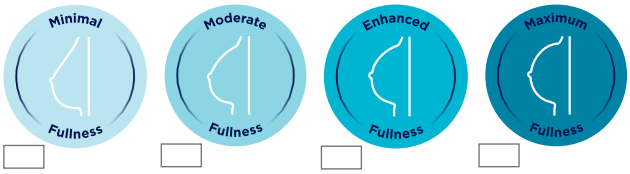
Incisional approach ☐ IM ☐ PA ☐ AX

Pocket location ☐ Subpectoral ☐ Subfascial ☐ Subglandular

Mastopexy ☐ Yes ☐ No

NOTES

DESIRED OUTCOME



☐ ☐ ☐ ☐

IMPLANT STYLE

☐ ***Natrelle*** INSPIRA® Cohesive

☐ ***Natrelle*** INSPIRA® SoftTouch

☐ ***Natrelle*** INSPIRA® Responsive

☐ Other

RIGHT IMPLANT SELECTED

Size (volume, width/diameter, projection)_____

Serial No. _____

Sizer style _____

LEFT IMPLANT SELECTED

Size (volume, width/diameter, projection)_____

Serial No. _____

Sizer style _____

SPECIFIC LIMITATIONS DISCUSSED

☐ Some residual asynnetries inevitable

☐ No guarantee of cup size

☐ Sensory loss, partial or complete on breast

☐ Warranty

☐ Palpable or visible edges of implant

☐ Other

Please see Important Safety Information on next page, including Boxed Warning.

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NATRELLE® BREAST IMPLANTS IMPORTANT SAFETY INFORMATION

WARNINGS

- **Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery**
- **Breast implants have been associated with the development of a cancer of the immune system called breast implant–associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL**
- **Patients receiving breast implants have reported a variety of systemic symptoms, such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases, and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement**

INDICATIONS

Natrelle® Silicone-Filled Breast Implants and *Natrelle* INSPIRA® Breast Implants are indicated for women for the following:

- **Breast augmentation for women at least 22 years old for silicone-filled implants and breast augmentation for women at least 18 years old for saline-filled implants.** This includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery
- **Breast reconstruction.** This includes primary reconstruction 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. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery

CONTRAINDICATIONS

Breast implant surgery should not be performed in:

- Women with active infection anywhere in their body
- Women with existing cancer or precancer of their breast who have not received adequate treatment for those conditions
- Women who are currently pregnant or nursing

ADDITIONAL WARNINGS

- See Boxed Warning in bold type above
- **Avoid damage during surgery:** Care should be taken to avoid the use of excessive force and to minimize handling of the implant. Forcing of implants through too small an opening or applying concentrated localized pressure on the implants may result in localized weakening of the breast implant shell, potentially leading to shell damage and possible implant rupture. An incision should be of appropriate length to accommodate the style, size, and profile of the implants. Use care when using surgical instruments in proximity with the breast implant
- Follow recommended fill volumes for saline implants to decrease possibility of shell wrinkling and crease-fold failure

PRECAUTIONS

Safety and effectiveness have not been established in patients with the following:

- Autoimmune diseases (eg, lupus and scleroderma)
- A compromised immune system (eg, currently receiving immunosuppressive therapy)
- Planned chemotherapy or radiation following breast implant placement
- Conditions or medications that interfere with wound healing and blood clotting
- Reduced blood supply to breast tissue
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery

ADVERSE EVENTS

Possible adverse events with breast implant surgery include implant rupture with silicone implants, implant deflation with saline-filled implants, capsular contracture, reoperation, implant removal, pain, changes in nipple and breast sensation, infection, scarring, asymmetry, wrinkling, implant displacement/migration, implant palpability/visibility, breastfeeding complications, hematoma/seroma, implant extrusion, necrosis, delayed wound healing, infection, breast tissue atrophy/chest wall deformity, calcium deposits, and lymphadenopathy. Other uncommon systemic conditions have been reported with breast implants.

For more information, please see the full Directions for Use at www.allergan.com/products.

To report a problem with *Natrelle*® Breast Implants, please call Allergan® at 1-800-624-4261.

The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Allergan®.

Intraoperative Breast Implant Sizers Important Information

INDICATIONS

The *Natrelle*® Silicone Sizer and the Allergan Saline Sizer are indicated for single use only for temporary intraoperative insertion in the surgical pocket to evaluate and assist in determining the final breast implant size/volume. The *Natrelle*® Re-sterilizable Silicone Breast Implant Sizer is used during breast augmentation or reconstruction procedures to assist the surgeon in determining the appropriate size of a breast implant to use.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS

All sizers are contraindicated for use as long-term breast implants or tissue expanders. The *Natrelle*® Silicone Sizer and the Allergan Saline Sizer are contraindicated for multiple patient use or multiple sterilizations.

WARNINGS

Sizers are designed for temporary intraoperative use only and are NOT long-term implants. DO NOT alter, insert, or attempt to repair a damaged sizer. DO NOT reuse the *Natrelle*® Silicone Sizer or the Allergan Saline Sizer, which are for single use only. The Silicone Sizers may rupture and release silicone gel. Infection, necrosis, hematoma/seroma, and pain may occur following any type of surgery. Minute quantities of silicone gel may diffuse through the elastomer envelope.

PRECAUTIONS

The surgeon must carefully evaluate patient suitability and be knowledgeable about the use of this device. DO NOT expose the sizer to contaminants. Avoid damaging the sizer with surgical instruments (eg sharp, blunt, or cautery devices). DO NOT attempt to repair damaged products. DO NOT damage the sizer by overhandling, manipulation, or excessive force. Maintain a sterile backup sizer during surgery.

ADVERSE EVENTS

Adverse events and/or complications may include sepsis, hemorrhage, thrombosis, bleeding, and/or infection.

For more information, please visit www.allergan.com/products.
To report a problem, please call Allergan at 1-800-433-8871.

Intraoperative Breast Implant Sizers are available by prescription only.

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