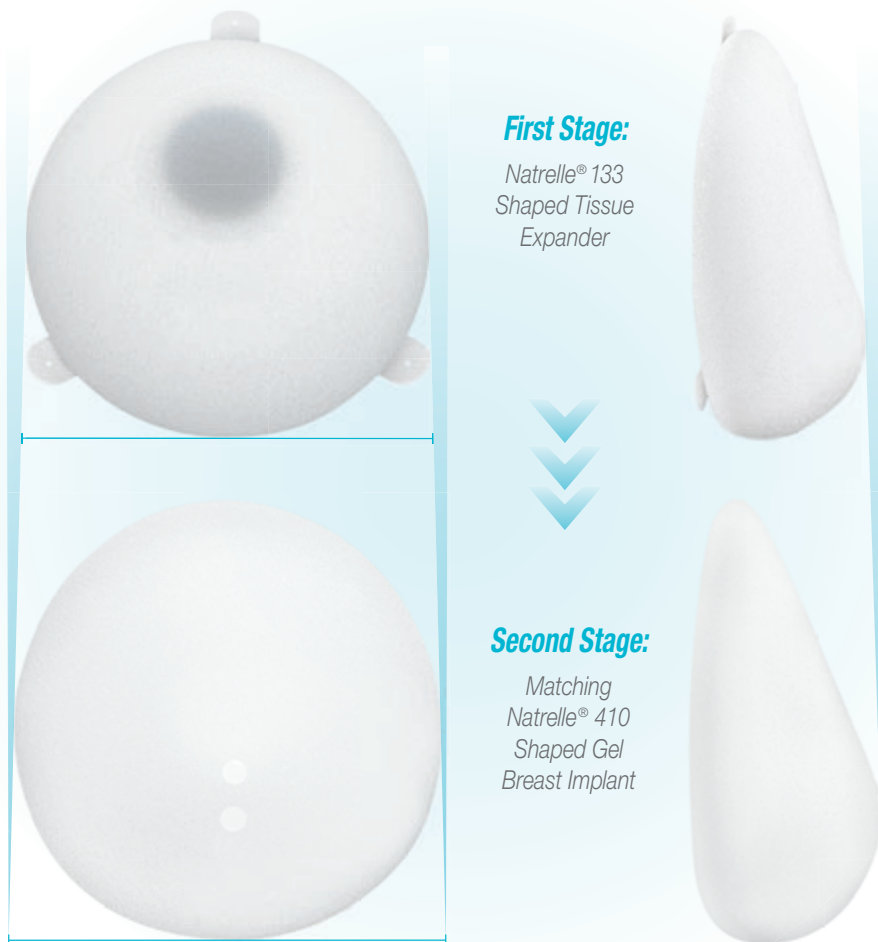


# Made *to* Match.

## Guide to the *Natrelle*® 410 Two-Stage Breast Reconstruction System



*Natrelle*® **410**

TWO-STAGE BREAST RECONSTRUCTION SYSTEM

Please see Indications and Important Safety Information inside.

## Key Contributors



### Allen Gabriel, MD

A board-certified plastic surgeon, Allen Gabriel, MD, practices in Vancouver, WA, with PeaceHealth Medical Group. Dr Gabriel is chief of Plastic and Maxillofacial Surgery at Southwest Washington Medical Center in Vancouver, WA, and associate professor at Loma Linda University, Department of Plastic Surgery, in Loma Linda, CA. He obtained his MD degree from the University of Nevada School of Medicine and completed his residency at the Integrated Plastic Surgery Residency Program at Loma Linda University. He completed advanced training in breast and aesthetic surgery at Baptist Hospital in Nashville, TN, and specializes in aesthetic and breast surgery, including breast reconstruction following mastectomy, breast augmentation, and revisions. Since 1995, Dr Gabriel has authored more than 3 dozen abstracts and chapters in peer-reviewed publications.



### Patricia McGuire, MD

Patricia McGuire, MD, is a board-certified plastic surgeon in private practice with Parkcrest Plastic Surgery in St Louis, MO. She attended medical school at the University of Missouri-Kansas City, did her general surgery residency at Jewish Hospital, Washington University in St Louis, and completed her plastic surgery residency at St Louis University. She specializes in cosmetic and reconstructive surgery of the breast. Dr McGuire was a principal investigator in the *Natrelle*® 410 study and has performed over 600 surgeries using shaped devices in breast augmentation and reconstruction, both in primary and revision procedures.

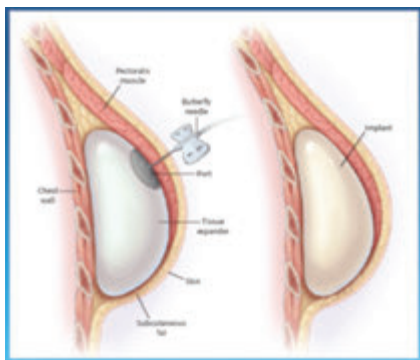


### James Namnoum, MD, FACS

James Namnoum, MD, FACS, is board-certified in Plastic and Reconstructive Surgery and practices in Atlanta, GA. He is codirector of the Atlanta Breast Symposium, an executive council board member for Allergan Breast Aesthetics, an assistant clinical professor at Emory University, and medical director of AYA Medical Spa. Dr Namnoum has participated as an investigator of *Natrelle*® 410 breast implants. He is copresident of Innovative Biologics, a research company investigating the development of biologically integrated implants for use in breast reconstruction.

# The Natrelle® 410 Two-Stage Breast Reconstruction System

The Natrelle® 410 Two-Stage Breast Reconstruction System is *Made to Match* with the Natrelle® 133 Tissue Expander and the Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implant, engineered with precision for a precise pocket and a tight fit. Once in place, the Natrelle® 410 Shaped Gel Breast Implant is designed to provide an anatomical look that holds its shape and provides lasting satisfaction. The Natrelle® 410 Two-Stage Breast Reconstruction System requires a biodimensional method of planning, which represents a paradigm shift from the volumetric thinking previously used with round implants, because shaped devices are selected based on each patient's unique anatomic dimensions.<sup>1</sup>



Breast reconstruction with tissue expander and implant.<sup>2</sup>

The Natrelle® 410 Two-Stage Breast Reconstruction System offers an anatomically shaped breast implant with a precisely matched shaped tissue expander. The anatomical shape of the Natrelle® 410 Shaped Gel Breast Implant provides upper pole fullness, a gradual slope, and lower pole contour to mirror the shape (curve) of a woman's breast.<sup>3,4</sup>

The Style 133 Tissue Expander has a BIOCELL® textured surface, which, together with suture tabs, helps anchor the device in place to help minimize the chance of rotation.<sup>1,5</sup>

The tissue expander has an integrated port that can be easily identified by its magnetic finder, facilitating the filling process.<sup>6</sup> After expansion is complete and the expander is exchanged for the permanent implant, patients benefit from the *Made to Match* implant.

The Natrelle® 410 breast implant is composed of a highly cohesive, form-stable gel that is designed to be just firm enough to retain its shape and prevent downward migration, or migration out of the capsule, over time.<sup>7</sup>

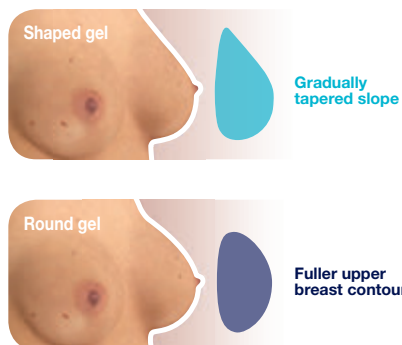
Both the gel implant and its matching expander are available in a wide variety of sizes and projections that mirror many breast shapes and chest dimensions.

By allowing preferential expansion of the lower pole, the anatomical Style 133 Tissue Expander provides a gradual contour to the upper pole.<sup>3</sup> Its *Made to Match* Natrelle® 410 implant helps patients achieve the aesthetic shape they seek, with a look that is different from that produced by round implants.

"I think that the design characteristics of the Natrelle® 410 implants cut a maximal projection probably a little lower than the nipple," says James Namnoum, MD, FACS, an Atlanta, GA, plastic and reconstructive surgeon who has worked extensively with the Natrelle® 410 Two-Stage Breast Reconstruction System.

## Proven safety profile

The Natrelle® 410 implant has an excellent safety profile, demonstrated by results through 7 years from the pivotal study that included a cohort of 225 women who received primary breast reconstruction.<sup>8</sup> It is an ongoing prospective, 10-year, multicenter, single-arm, observational study designed to evaluate the safety and effectiveness of the Natrelle® 410 in augmentation, reconstruction, and revision surgery.<sup>9</sup>



*"I think the idea of a system is really clever. I've always used it like a 'team'. I know the dimensions of the expanders, and with the Natrelle® 410 implant, you know you can get within 0.5 cm of the width of the expander. It's easy to remember, and it helps me achieve consistent results."*

*-Patricia McGuire, MD*

## Natrelle® Breast Implants Important Information INDICATIONS

Natrelle® Breast Implants are indicated for women for the following:

- **Breast reconstruction.** Breast reconstruction 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.

Please see Natrelle® Breast Implants Important Safety Information on following pages.



TWO-STAGE BREAST RECONSTRUCTION SYSTEM

Reported Adverse Events Over 7 Years<sup>8</sup>

Complication	Kaplan-Meier Risk (%) (n = 225)
Palpability/Visibility	0.5%
Tissue/Skin necrosis	0.5%
Wrinkling/Rippling	3.1%
Malposition	3.6%

High satisfaction rate among physicians and patients

Natrelle® 410 breast implants are the #1 selected shaped implants among surgeons in the United States.<sup>9</sup> Approved by the US Food and Drug Administration in February 2013, for use in the United States, the Natrelle® 410 has been placed in 17,000 patients in clinical trials.<sup>9</sup>

Results of the pivotal trial show that 7 years after implantation, the vast majority of patients and physicians (95% and 94%, respectively) remained satisfied with the Natrelle® 410. Out of 149 primary reconstruction cases, 95.3% of patients who rated their satisfaction at 7 years were still satisfied with their results. Likewise, physicians were still satisfied with results in 94.6% of cases at 7 years.<sup>9</sup>

“I ask my patients at every visit if they are satisfied with the look of their breast,” says Allen Gabriel, MD, chief of plastic and maxillofacial surgery at Southwest Washington Medical Center in Vancouver, WA, and associate professor, Department of Plastic Surgery, at Loma Linda University, “And they say, ‘Yes.’”

Consistent results

Surgeons rely on tools and devices to help them provide successful outcomes. Using a system in which it is easy to match the tissue expander to a corresponding breast implant frees surgeons to focus on perfecting breast reconstruction. The potential for variability is particularly challenging in breast reconstruction, given each patient’s unique disease requirements and consequent effects on the

ability to preserve key anatomic landmarks. It is helpful when, despite the wide range of choices, there is a system engineered with precision for a precise pocket and a tight fit.

Natrelle® 410 implants and Style 133 Tissue Expanders, which make up the Natrelle® Two-Stage Breast Reconstruction System, are Made to Match. This begins with the uniform anatomical shape of the Natrelle® 410 implant and its Made to Match Style 133 Tissue Expander—both of which are created using similarly shaped molds. At the second surgery, when the tissue expander is removed from the expanded pocket, it is replaced with a permanent implant designed to fit into the precise pocket like a hand in a glove.<sup>1</sup> When the tissue expander is underexpanded, it prepares a snug pocket that is designed to minimize rotation of the expander to fit the matched shape of the Natrelle® 410 implant.

As Patricia McGuire, MD, a board-certified plastic surgeon in private practice with Parkcrest Plastic Surgery in St Louis, MO, who has conducted over 600 surgeries with shaped implants, notes, “I think the idea of Made to Match implants and expanders is really clever. I’ve always used them like a ‘team’. I know the dimensions of the expanders, and with the Natrelle® 410 implant, you know you can get within 0.5 cm of the width of the expander. It’s easy to remember and it helps me achieve consistent results. There are 45 options for size; the design of the tissue expander and implant working together makes that choice a little bit easier. With this system, the tissue expander is telling you what implant to use, and that’s a lot less intimidating.”



Tissue Expander Selected: Natrelle® Style 133MV (600 cc); implanted for 4 months  
Implant Selected: Natrelle® 410 Style MF 470

Photos provided by Scott Spear, MD. Individual results may vary.

Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

Breast implant surgery should not be performed in:

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

WARNINGS

AVOID DAMAGE DURING SURGERY

- Care should be taken to avoid the use of excessive force and to minimize handling of the implant during surgical insertion.
- Care should be taken when using surgical instruments in proximity with the breast implant, including scalpel, sutures, and dissection instrumentation.

- Do not treat capsular contracture by closed capsulotomy or forceful external compression, which will likely result in implant damage, rupture, folds, and/or hematoma.
- Use care in subsequent procedures such as open capsulotomy, breast pocket revision, hematoma/seroma aspiration, and biopsy/lumpectomy to avoid damage to the implant.
- Do not place drugs or substances inside saline-filled implants other than sterile saline for injection. Do not inject through the implant shell.
- Do not contact the implant with disposable, capacitor-type cautery devices.
- Do not alter the implants or attempt to repair or insert a damaged prosthesis.
- Do not immerse the implant in povidone-iodine solution. If povidone-iodine is used in the pocket, ensure that it is rinsed thoroughly so no residual solution remains in the pocket.
- Do not reuse or resterilize any product that has been previously implanted. Breast implants are intended for single use only.

## Case Study #1: Patricia McGuire, MD

### Patient assessment

This 45-year old patient had invasive ductal cancer of her right breast. As she had a significant family history of cancer, she elected to undergo bilateral mastectomy and requested immediate reconstruction with a tissue expander (TE) followed by permanent implants.

This was a great candidate for Natrelle® 410, as she had small breasts with a proportionate BMI. She wanted an anatomical look to her breasts and said that she would love to not have to wear a bra.

### KEY PATIENT MEASUREMENT

- Breast base width (BW): 12.5 cm

### Preoperative plan

- The patient wore a 36A bra size and wanted to be a little bigger postoperatively. Because of her 12.5 cm breast width, a 300 cc Style 133MV expander with a width of 12 cm was chosen—slightly smaller than the implant, so the implant would fit snugly in the pocket

### Surgical technique

#### FIRST STAGE:

#### DELAYED RECONSTRUCTION WITH TISSUE EXPANDER

- At surgery, this patient had total muscle coverage of her expanders

- She did not require any acellular dermal matrix (ADM) support in surgery
- The Natrelle® 133 TE was filled to 180 cc in the operating room
- Drains were inserted in each side and left in place for 11 days. They were removed after the drainage was less than 30 cc over a 24-hour period
- The patient wore a bra postoperatively for comfort

I believe in an active recovery, so I encouraged activity as long as she was comfortable. She returned to work 12 days post operation.

- Two weeks post-op, the patient's Natrelle® 133 TE was expanded to 300 cc. Her expansions were worked around sessions of postoperative chemotherapy. Her expanders were then left in place until she finished chemotherapy

### Surgical technique

#### SECOND STAGE: IMPLANT EXCHANGE

Given that her expanders looked good, the plan for her second stage was to place a Natrelle® 410 Style FF 375 implant given her preoperative breast width of 12.5 cm, which was slightly wider than the expander.

I used a full-height device because (1) our oncologic surgeons tend to skeletonize the chest wall and (2) the taller implant with a gradual slope fills the upper pole with a gradual slope.

- At implant exchange, she had good adherence of the expander to the tissue capsule. The inside of the capsule had developed in a “mirror image” capsule to the BIOCELL® surface of her expander, so no capsulectomy was necessary
- The patient had an inferior capsulotomy with division of the pectoralis muscle insertion and a superior capsulotomy to allow the superior portion of the implant to lie smoothly in the pocket
- Drains were placed in each breast for 7 days
- The Natrelle® 410 breast implant provided her with the shape she desired with good lower pole projection

### Outcomes

The patient did not choose to undergo nipple areola reconstruction. She has since done well and is pleased with her appearance.

This is a straightforward case where I allowed the patient's anatomy to drive the decision-making. I used her BW to determine the TE and then the known dimension of the TE to determine which style of Natrelle® 410 implant to use. I was able to meet this patient's wishes of an anatomically shaped breast, slightly larger than her preoperative breast, and this result has held up for over 5 years.



Individual results may vary.

**“I think we’re very lucky right now to be in an era when there are choices for surgeons and patients. Several different implants are available, with different shell characteristics, different textures, different fills, and different cohesiveness of the gels. There may be advantages and disadvantages to each of these for different surgeons and patients. In my hands, I find that I can use the Natrelle® Two-Stage Breast Reconstruction System in 90% of my patients. I haven’t used anything except the Style 133 Tissue Expander in about 17 years. I’ve been following patients for many years, and these results don’t just look good 6 months, a year, or 2 years after surgery—we have postoperative results that still look good after 7 years.”**

### Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS (continued)

- Do not place more than one implant per breast pocket.
- Do not use the periumbilical approach to place the implant.

Please see additional Natrelle® Breast Implants Important Safety Information on pages 8 to 10.

Natrelle® 410

TWO-STAGE BREAST RECONSTRUCTION SYSTEM

## Natrelle® 133 Tissue Expander BIOCELL® Texturing

The BIOCELL® shell covering the Style 133 Tissue Expander has an open-pore texture of irregularly spaced cuboid wells.<sup>10</sup> BIOCELL® is a macrotextured surface that is created using a lost salt technique.<sup>11,12</sup>

The cuboid depressions of the textured surface vary in size from 200 µm to 500 µm wide and 100 µm to 200 µm deep.<sup>11</sup>

When viewed by electron microscopy, the surface of the capsule is a mirror image of the textured surface of the device.<sup>12</sup>

BIOCELL® textured surface facilitates tissue expander adherence to the surrounding tissue,<sup>11-13</sup> as first demonstrated in Maxwell's landmark study on breast reconstruction with

BIOCELL® textured surface, integrated-valve, anatomical tissue expanders.

Functionally, adherence of the BIOCELL® textured surface to the periprosthetic breast capsule promotes immobility of the expander.<sup>14</sup> Adherence can be observed when the tissue expander is exchanged for the implant during the second stage of surgery.<sup>15</sup> In the Maxwell study, 98% of BIOCELL® textured expanders, on average, adhered to the capsule at 5 months.<sup>10</sup> In order to remove the tissue expander, the capsule must be carefully peeled away from the tissue expander, disengaging it in preparation for the pocket to receive the permanent *Natrelle*® 410 implant.<sup>10</sup>

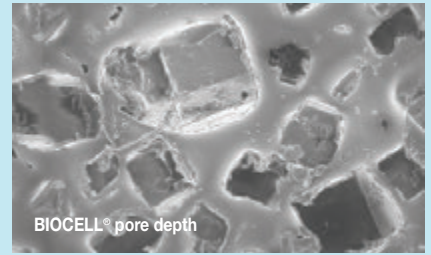


Photo provided by Dr G. Patrick Maxwell.

Seven-year results from the pivotal trial of the *Natrelle*® 410 Shaped Gel Breast Implant demonstrated a 10.7% rate of capsular contracture in primary breast reconstruction patients.<sup>8</sup> Malposition occurred infrequently in the trial, at a rate of 3.6% in primary reconstruction.<sup>8</sup>

“The texture of the tissue expander plays an important role,” says Dr. Gabriel. “I believe that the texture is really important in helping to minimize rotation, and, along with the tabs, we can secure the tissue expander to minimize rotation during the first stage.”

### Bidimensional planning is key

Bidimensional planning takes the patient's unique anatomy and measurements into consideration when selecting implant and tissue expander size.<sup>8</sup> The patient's base width is the key factor in selecting both the shaped tissue expander and shaped *Natrelle*® 410 implant. The tissue expander creates a tight pocket for the anatomic implant in order to help minimize rotation. Once implanted, the *Natrelle*® 410 implant creates an anatomic shape from the beginning—that is maintained over time.

### Natrelle® 133 Tissue Expanders with/without Suture Tabs and with Magna-Site® Injection Sites Important Information

#### Indications

*Natrelle*® 133 Tissue Expanders are indicated for:

- Breast reconstruction following mastectomy.
- Treatment of underdeveloped breasts.
- Treatment of soft tissue deformities.

#### IMPORTANT SAFETY INFORMATION

##### CONTRAINDICATIONS

*Natrelle*® 133 Tissue Expanders **SHOULD NOT** be used in patients:

- Who already have implanted devices that would be affected by a magnetic field (e.g., pacemakers, drug infusion devices, artificial sensing devices).
- Whose tissue at the expansion site is determined to be unsuitable.
- Who have an active infection or a residual gross tumor at the expansion site.
- Undergoing adjuvant radiation therapy.
- Whose physiological condition (e.g., sensitive over or underlying anatomy, obesity, smoking, diabetes, autoimmune disease, hypertension, chronic lung

or severe cardiovascular disease, or osteogenesis imperfecta) or use of certain drugs (including those that interfere with blood clotting or affect tissue viability) poses an unduly high risk of surgical and/or postoperative complications.

- Who are psychologically unsuitable.

#### WARNINGS

- **DO NOT** use *Natrelle*® 133 Tissue Expanders in patients who already have implanted devices that would be affected by a magnetic field (see Contraindications), because the MAGNA-SITE® integrated injection site contains a strong rare-earth, permanent magnet. Diagnostic testing with Magnetic Resonance Imaging (MRI) is contraindicated in patients with *Natrelle*® 133 Tissue Expanders in place.
- **DO NOT** alter the tissue expander or use adulterated fill. Fill only with sterile saline for injection as described in INSTRUCTIONS FOR USE. **DO NOT** expose to contaminants.
- **DO NOT** expand if the pressure will compromise wound healing or vasculature of overlying tissue, or beyond patient or tissue tolerance. Stop filling immediately if tissue damage, wound dehiscence, abnormal skin pallor, erythema, edema, pain, or tenderness are observed.

The selected widths for both the tissue expander and the implant are determined by the base width of the breast—the width of the expander should be 0.5 cm to 1 cm smaller than that of the intended implant.<sup>1,9</sup> While most surgeons select the size of the implant first and work backwards to select the size of the tissue expander, the matched dimensions of both devices simplify this process.

<b>Natrelle® 133 Shaped Tissue Expander</b>	<b>Natrelle® 410 Shaped Gel Breast Implant</b>	<b>0.5 cm or 1.0 cm Precision Match</b>
<i>Base Width</i>	<i>Base Width</i>	
11.0 cm	11.5 cm or 12.0 cm	✓
12.0 cm	12.5 cm or 13.0 cm	✓
13.0 cm	13.5 cm or 14.0 cm	✓
14.0 cm	14.5 cm or 15.0 cm	✓
15.0 cm	15.5 cm	✓

Since anatomically shaped implants add a new dimension of height to the existing dimensions of base width and projection that define round implants, biodimensional planning requires a paradigm shift in surgeons' thinking.<sup>1</sup> It requires calculating shape and dimension, in addition to thinking in terms of volume and cup size.<sup>3</sup>

Although first-stage breast reconstruction establishes the blueprint for the final implant, many surgeons find it helpful to envision the final implant results first. Use the patient's breast width to determine the implant width. The size of the tissue expander should be 0.5 cm to 1 cm smaller than the implant size.<sup>9</sup> Final expansion should closely approximate the desired result with the implant to ensure that the implant will fit snugly within the pocket. Avoid over expansion with the tissue expander for a proper fit and to help minimize device rotation.<sup>15</sup>

Biodimensional planning is a comprehensive approach that begins with preoperative planning and incorporates additional surgical elements to achieve the best possible aesthetic results. It is always advisable to include the oncology surgeon in the patient's reconstructive surgery team in both preoperative planning and postoperative management.<sup>4</sup> This may also facilitate the use of the latest skin and nipple-sparing techniques in the mastectomy, laying the groundwork for a good reconstructive outcome.

"I took a course by Dr Pat Maxwell on biodimensional planning in the late 1990s that completely changed how I approached breast reconstruction: The focus of this approach is using the patient's anatomy to choose the tissue expander, and doing a precise dissection, just like you would in breast augmentation," says Dr McGuire. "Planning the

second stage carefully, educating the patient, and using the patient's dimensions to choose the appropriate implant for her body really makes a big difference in getting results that look good—and look good for a long time."

**Which patients are appropriate candidates for the Natrelle® 410 breast implants in two-stage breast reconstruction?**

The anatomically shaped Natrelle® 410 implant and its *Made to Match* Style 133 Tissue Expander are appropriate for almost all candidates in implant-based breast reconstruction who would otherwise receive a round implant. The primary exception is the patient with BMI ≥ 29, who usually requires more pronounced projection and a wider base width than is available, and may encounter expansion difficulties.<sup>15</sup>

**Natrelle® 133 Tissue Expanders**  
**IMPORTANT SAFETY INFORMATION (continued)**  
**WARNINGS (continued)**

- Active infection anywhere may increase risk of periprosthetic infection. Postoperative infections should be treated aggressively. Unresponsive or necrotizing infection may require premature removal.
- Natrelle® 133 Tissue Expanders are temporary, single use only devices, and are not to be used for permanent implantation or beyond 6 months. Tissue expansion in breast reconstruction typically requires four to six months.
- When using suturing tabs be careful to avoid piercing the shell. Use a new one if damage occurs.

**PRECAUTIONS**

Active infections may need to be treated and resolved before surgery. Allergan relies on the surgeon to know and follow proper surgical procedures and carefully evaluate patient suitability using standard practice and individual experience.

Avoid damage to the tissue expander and use a sterile back-up in case of damage. Pay careful attention to tissue tolerance and hemostasis during surgery. Expansion should proceed moderately and never beyond patient or tissue tolerance. Avoid contamination in any postoperative procedure.

Please see additional Natrelle® 133 Tissue Expanders Important Safety Information on back page.



TWO-STAGE BREAST RECONSTRUCTION SYSTEM

**Patients who may be appropriate for a Natrelle® 410 shaped implant include:**

- Patients who desire a proportionate look with less upper pole fullness<sup>7</sup>

- Patients with proportionate height/weight and breast size<sup>15</sup>
- Patients for whom no radiation treatments are planned<sup>6,16</sup>
- Patients who received either a unilateral

or a bilateral therapeutic or prophylactic mastectomy<sup>15</sup>

- Patients who may especially benefit aesthetically from an anatomically shaped implant include those with thoracic or chest wall deformities<sup>1</sup>

**Case Study #2: Allen Gabriel, MD**

**Patient assessment**

This 56-year old woman had a diagnosis of left breast-infiltrating ductal carcinoma stage IIIA. In the next month, she underwent a left lumpectomy with left axillary node dissection (in which 16 nodes were removed), followed by adjuvant chemotherapy and radiation therapy, which she completed 7 months later. As both her mother and her aunt had breast cancer, she decided that she did not wish to undergo continued regular screening and decided on a bilateral mastectomy.

*A complicating factor was that she had severe skin changes resulting from damage from radiation therapy. Successful reconstruction depended on developing a source of new vascularized tissue.*

**KEY PATIENT MEASUREMENTS**

- Sternal notch-to-nipple (SN-N) right was 26.5 cm; left was 25 cm.
- Breast base width (BW) was 16 cm

**Preoperative plan**

- Since the nipple areolar complex was going to be removed on the left side, and to avoid

further shrinking of the skin envelope, the plan was to replace the missing area with new vascularized skin, using a latissimus flap reconstruction with a tissue expander for her left side

- Taking into consideration the patient's dimensions and her desire to stay close to the same-size breasts, a Natrelle® 410 Style FF 740 implant was selected as most appropriate for the final reconstruction
- A Natrelle® Style 133MV (600 cc) tissue expander was chosen, as it was slightly narrower and shorter in height than the final implant

**Surgical technique**

**FIRST STAGE: IMMEDIATE RECONSTRUCTION WITH TISSUE EXPANDER**

- The patient underwent a mastectomy that spared her right nipple and skin on her left breast. She then immediately had her breasts reconstructed with Natrelle® Style 133MV (600 cc) tissue expanders

- An 8 x 16 cm ADM was used bilaterally for tissue support as well as in her left latissimus dorsi myocutaneous flap 14 months later
- During the surgery, 240 cc of saline was inserted in the TE. The expansion was completed 4 weeks later at a final volume of 600 cc

**Surgical technique**

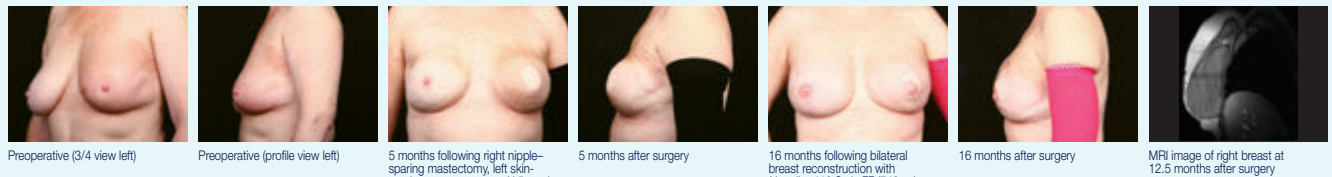
**SECOND STAGE: IMPLANT EXCHANGE**

Bilateral breast reconstruction with Natrelle® 410 Style FF (740 cc) implants was performed on February 27, 2013.

- Fat was injected into the upper, medial, and lateral poles
- Bilateral nipple reconstruction was completed 16 months later

**Outcomes**

Since then, the patient has been doing extremely well, given that she had received radiation prior to the reconstruction surgery on her left side. She had an MRI in March 2014, following a car accident. The implant remained intact and continues to remain at Baker Grade I rating bilaterally.



***“What makes using the Natrelle® 410 Two-Stage Breast Reconstruction System so much fun is the true artistry of plastic surgery. What you’re doing is trying to reconstruct a breast from scratch, giving it the most anatomical shape with everything that you have at hand. We can control the height, we can control the width, and we can control the projection. So we’re controlling all 3 dimensions of the breast that we need to control to provide the best breast for that particular patient.”***

**Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION (continued)**

**WARNINGS (continued)**

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

**PRECAUTIONS**

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

- Autoimmune diseases (e.g., lupus and scleroderma).

- A compromised immune system (for example, currently receiving immunosuppressive therapy).
- Planned chemotherapy following breast implant placement.
- Planned radiation therapy to the breast 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.



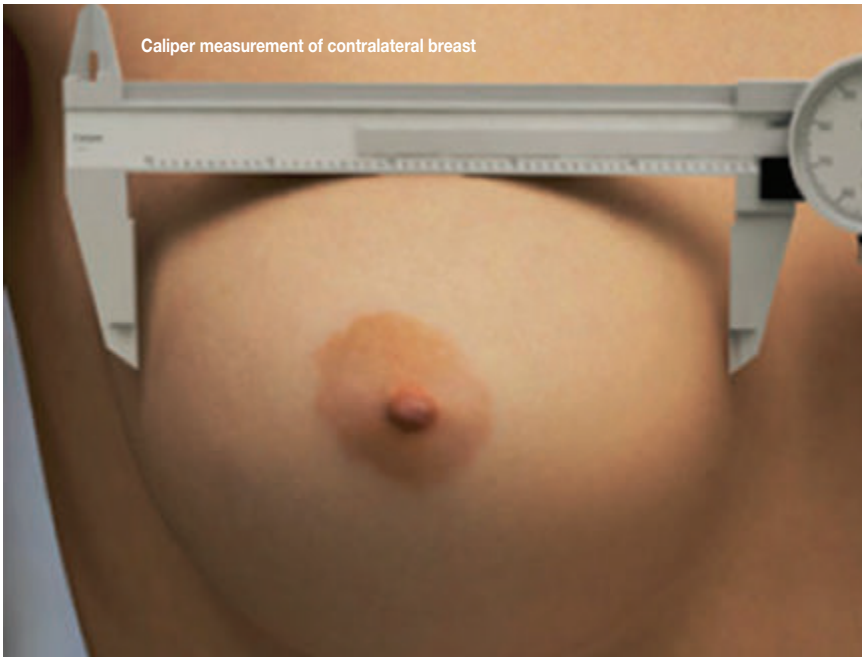


Photo from Natrelle® 410 Interactive Surgery Planner.

**“I wanted more consistency in my results, and that’s how I became interested in an approach that could help me plan better. Dimensional planning gives you an opportunity to think, so you can get more consistent results. It’s all in the thinking.” –James Nannoum, MD, FACS**

### Selecting the appropriate tissue expander and implant

Key to the success of the Natrelle® 410 Two-Stage Breast Reconstruction System is how well the *Made to Match* Style 133 Tissue Expander customizes the pocket for the Natrelle® 410 implant. Appropriate implant size is based on the patient’s individual anatomy and desired aesthetic outcome.<sup>1</sup>

Tissue expander size is selected based on the base width of the contralateral natural breast, in the case of a unilateral mastectomy, which is best measured using calipers.<sup>4,15</sup> In the case of a bilateral mastectomy, the patient’s chest width is measured from the midsternum to the anterior axillary line.<sup>15</sup>

There are 3 styles of tissue expanders available for the Natrelle® 410 Two-Stage Breast Reconstruction System: short, moderate, and

full, each with variable projections (Styles SV, MV, and FV). The first letter refers to the height, and the second refers to the projection. Several sizes are available for each style, and each is available with or without tabs. Altogether, there are 36 tissue expander size options.

There are 4 available styles for the Natrelle® 410 implant (MM, MF, FM, FF). They are available in 2 heights—moderate and full (the first letter of the style represents the height), and each height is available in 2 projections—moderate and full projection (the second letter of the style represents the projection).<sup>8</sup> Several sizes are available within each style, leading to a total of 45 Natrelle® 410 implant size options.

### Expansion phase

The time it takes to reach full expansion will vary depending upon physician preference and patient treatment requirements. Some

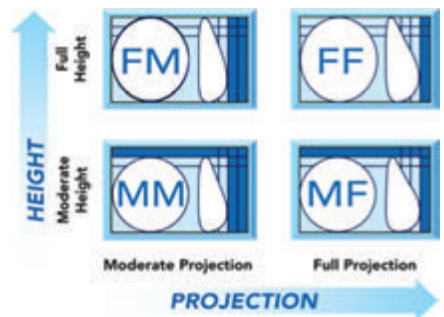
surgeons prefer to complete the expansion in as little as 2 weeks, with only a few inflations, while others may coordinate expansion with the patient’s chemotherapy schedule and comfort level, postponing expansion until 4 to 6 months after the first surgery. Generally, however, expansion is completed within 2 to 4 months, with approximately 4 inflations.<sup>4,10,15</sup>

The maximum recommended time for tissue expansion with the Natrelle® 133 Tissue Expander is 6 months.<sup>9</sup>

### Precise pocket preparation

The primary goal in tissue expander placement is creation of a snug pocket in the location of the final implant. Precise dissection of the pocket during the first stage minimizes the risk of expander rotation and helps optimize pocket creation.<sup>7,15</sup> The precision of pocket dissection is a key differentiator for anatomical implants.

To achieve the best result, the shape of the pocket should closely mirror the form of the tissue expander and be both shorter and narrower in size than the planned permanent implant. Minimal dissection of the upper pole allows the tissue expander to have maximal surface contact with the tissues lining the pocket, promoting mild tissue adherence to the open pores of the BIOCELL® textured surface.<sup>5</sup> As the expander is inflated, it will maintain contact with the walls of the pocket, optimizing the opportunity for adherence.



### Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION (continued)

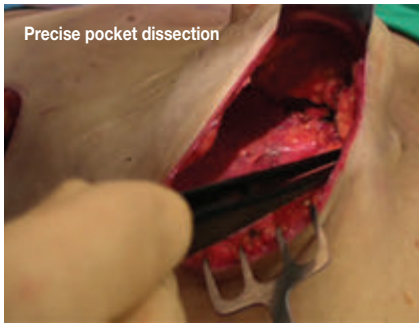
#### ADVERSE EVENTS

Key adverse events are reoperation, implant removal with or without replacement, implant rupture with silicone-filled implants, implant deflation with saline-filled implants, and capsular contracture Baker Grade III/IV.

Please see additional Natrelle® Breast Implants Important Safety Information on next page.



TWO-STAGE BREAST RECONSTRUCTION SYSTEM



Precise pocket dissection



Complete muscle coverage of the TE

Photos courtesy of G. Patrick Maxwell, MD.

The entire condition of the pocket is important for a successful outcome. Several other elements of pocket preparation, unique

to anatomical devices, may also help surgeons optimize outcomes:

- Once the pocket is adequately dissected during the first stage of surgery, confirm that the tissue expander is secure in the pocket in order to help minimize rotation<sup>8</sup>
- The size of the incision should be adequate to insert the implant without deforming it or fracturing the gel. The incision is usually larger than that required for a round implant — at least 5 cm wide<sup>8</sup>
- The dimensions of the pocket should allow the implant to be placed flat on a smooth surface<sup>8</sup>
- Avoiding overexpansion during the first stage is key to creating a snug pocket
- Once the tissue expander is selected and the pocket is expanded, there is still opportunity to vary the choice of implant during second-stage surgery, particularly with respect to height and projection. This is especially important because a patient may change her mind once she can react to her new shape
- Ensure hemostasis by visualization and electrocautery, and irrigate the pocket with antibiotics to reduce the risk of infection<sup>17</sup>

In the second stage, the use of drains is recommended to reduce fluid accumulation

and potential rotation. The drains are best left in place for 5 to 8 days, or until fluid volume is reduced to < 30 cc per day.<sup>18,19</sup>

“I feel it is important to create a vascularized tissue surface within the pocket for the expander and implant,” says Dr Gabriel. “At the expander stage, even though I have the tab, I feel much better if I know the vascularized surface is touching the expander.”

### Conclusion

The *Made to Match* system simplifies breast reconstruction planning by pairing the *Natrelle*<sup>®</sup> 410 Shaped Gel Breast Implant with its anatomically shaped Style 133 Tissue Expander. Using the principles of biodimensional planning offers the patients options based on their own unique anatomic dimensions.<sup>1</sup>

The tissue expander and matched implant, with their anatomical shapes and wide range of sizes, help surgeons achieve an aesthetic look for their patients. At the same time, the Style 133 Tissue Expander, and the highly cohesive, form-stable gel of the *Natrelle*<sup>®</sup> 410 Implant, are engineered with precision for a precise pocket and a tight fit.

### *Natrelle*<sup>®</sup> Breast Implants IMPORTANT SAFETY INFORMATION (continued) ADVERSE EVENTS (continued)

Other potential adverse events that may occur with breast implant surgery include: asymmetry, breast pain, breast/skin sensation changes, capsular calcification, delayed wound healing, hematoma, hypertrophic scarring/scarring, implant extrusion, implant malposition, implant palpability/visibility, infection, nipple complications, redness, seroma, swelling, tissue/skin necrosis, wrinkling/rippling.

For more information see the full Directions for Use at [www.allergan.com/labeling/usa.htm](http://www.allergan.com/labeling/usa.htm) or call the Allergan Product Support line at 1-800-433-8871.

To report a problem with *Natrelle*<sup>®</sup>, please call Allergan Product Surveillance at 1-800-624-4261.

*Natrelle*<sup>®</sup> Breast Implants are available by prescription only.

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TWO-STAGE BREAST RECONSTRUCTION SYSTEM

# Made *to* Match.

## **Natrelle® 133 Tissue Expanders IMPORTANT SAFETY INFORMATION (continued)**

### **ADVERSE REACTIONS**

Deflation, tissue damage, infection, extrusion, hematoma/seroma, capsular contracture, premature explantation, displacement, effects on bone, pain, sensation, distortion, inadequate tissue flap, and inflammatory reaction.

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

For more information, please visit [www.allergan.com/labeling/usa.htm](http://www.allergan.com/labeling/usa.htm) or call the Allergan Product Support line at 1-800-433-8871.

*Natrelle*® 133 Tissue Expanders are available by prescription only.

*Natrelle*® **410**

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