Breast Augmentation
Packet - Allergan

- **Patient copies of post-op instructions are on top of the packet.**
- **If more than one page, staple them together and place one patient label on the first page only.**
- **No need to hole punch patient copies of post-op instructions. Just place instructions inside the chart.**

Pelosi Medical Center

BREAST AUGMENTATION
POST-OPERATIVE INSTRUCTIONS

INSTRUCTIONS

- A responsible adult must drive you home after surgery and help you at home for 1-2 days.
- Follow a balanced diet.
- Do not smoke, as smoking delays healing and increases the risk of complications

ACTIVITIES

- Refer to section "*Recipe for Quick Recovery*" on pages 2 and 3
- Do not drive until you have full range of motion with your arms and you are no longer taking pain medications (narcotics).
- Refrain from vigorous activity for 4 weeks. Body contact sports should be avoided for 6-8 weeks.
- Social and employment activities can be resumed in 3-10 days.
- You may begin special breast massage 1-2 weeks following surgery. This should be done for 5 minutes, 3 times/day during the first 2-3 post-operative months. Some patients may experience mild pain during the first week of massage; however, this will resolve in a short period of time. Dr. Pelosi or one of the nurses/medical assistants will instruct you on how to perform the massage. Be sure to ask if you are not told.

INCISION CARE

- Avoid exposing scars to sun for at least 12 months. Always use a strong sun block if sun exposure is unavoidable (SPF 30+).
- Keep steri-strips on; replace them if they come off.
- Keep incisions clean and inspect daily for signs of infection. Sutures are under your skin and will eventually dissolve.
- Do not take a tub bath while sutures are in place.
- You may pad the incisions with gauze for comfort.
- Wear garments (bra, ace wrap, taping) as directed by your surgeon. Do not wear an underwire bra.

WHAT TO EXPECT

- Expect some drainage onto the steri-strips covering the incisions.
- Maximum discomfort will occur in the first few days after surgery.
- You may experience some numbness of nipples & operative areas and a burning sensation in your nipples for about 2 weeks.
- You may experience temporary soreness, tightness, swelling and bruising in the incision area.
- Your breasts may be sensitive to stimulation for a few weeks.

APPEARANCE

- Most of the discoloration and swelling will subside in 4-6 weeks.
- Scars may be red for 6 months. In time, these usually soften and fade.

FOLLOW-UP CARE

- It is imperative that you be seen within 24-48 hours following surgery and then again on the 5^{th}-7^{th} post-op day.
- Continue with routine mammograms at a radiology center where technicians are experienced in the special techniques required with implants.

WHEN TO CALL THE OFFICE

- Call the office if you have any of the following: increased swelling or bruising, swelling and redness that continues after a few days; increased redness along the incision; severe or increased pain not relieved by medication; any side effects to medications (such as, rash, nausea, headache, vomiting); an oral temperature over 100.4 degrees; any yellowish or greenish drainage from the incisions or notice a foul odor; bleeding from the incisions that is difficult to control with light pressure; or loss of feeling or motion.

LONG TERM POST-OPERATIVE CARE:

- After the first 3 months, you should be seen by the surgeon 3-4 times for the first year and twice yearly for the next 5 years.
- As one ages, the breasts may have a tendency to fall, which can often be accelerated by the weight of the implants. Some of this may be avoided by wearing a bra as often as possible especially when doing impact-sporting activities.
- If you begin to feel that the breasts are becoming firmer, you should visit the office for a check-up any time during the first two years.

RECIPE FOR QUICK RECOVERY
(FOR PATIENT AND CARETAKER TO READ)

The secret to a successful quick recovery lies in COMPLIANCE. There is a method to the madness below – please do not DEVIATE from these instructions and the ORDER in which they are listed.

ARRIVING HOME FROM SURGERY

When you leave the surgery center the time clock starts! We want you to go home and take a 2-hour nap. That is all. Wake up and get moving! No more sleeping today. You can sit down and rest, but no more napping until bedtime.

Next, make sure you eat something substantial. Crackers are not enough.

If you were going to get sick from the anesthesia, it would have already happened. Nausea usually occurs within the first 3-4 hours after surgery, which you have now peacefully slept through!

If you feel nauseous, it is usually either because you took your medicine on an empty stomach or you are not drinking enough fluids. Make sure you eat something real – whatever you are craving. Make sure that you are doing more than taking just a sip of something here and there. If you normally drink a diet coke, drink a real coke or something with sugar. We need to jump start your system.

As soon as you have eaten, take one tablet of 800 mg Ibuprofen by mouth; wait 30 minutes and take a shower. Wash off the purple markings on the skin from surgery and wash your hair. The shower is magic to loosen things up, help eliminate the foggy feeling from anesthesia, and washing your hair gets your arms above your head.

After the shower, blow-dry your hair (move hands up to your head), and then move your arms above your head in a slow jumping jack type motion. Extend the arms straight out from the shoulders and, keeping the arms straight, touch the back of the hands together straight above the head. When the hands touch, the biceps muscles of the upper arm should touch your ears. **You need to do a set of 5 of these arm stretches every hour on the hour until bedtime**.

The next step is most important. **GET OUT OF THE HOUSE**; in the company of an adult, go shopping or walk around the mall. Go out to dinner. Close your own car door and put on your own seat belt. A change of scenery is a wonderful thing!

Try to keep stay awake until at least 10:00 pm.

If you must stay home, do normal things around the house: unload the dishwasher, make dinner, or read to the kids. Most importantly, **KEEP MOVING AND DO NOT LIE DOWN OR STAY STILL**.

Remember, you cannot hurt yourself through any type of normal activities. We have NO incentive to tell you to do something that would send you back to the operating room. By moving, you will feel better faster and reduce your risk of capsular contracture and another operation! It is important that you know and understand and get moving!

BEDTIME

Around 10:00 pm, make sure you take another 800 mg of Ibuprofen with food and 25 mg of Benadryl by mouth, which will help you sleep. During the night, you'll wake up when you roll onto your side, but because of the sedative effect of the Benadryl, you'll go right back to sleep.

You can do anything you want to make yourself comfortable. That may mean more showers, or more arm movements or lying on them more than once. Whatever makes you comfortable is fine.

POST-OP DAY 1

Pelosi Medical Center

BREAST AUGMENTATION
RECIPE FOR QUICK RECOVERY

Get up, eat breakfast and take one 800 mg of Ibuprofen by mouth. Give it 30 minutes and get in a nice warm shower. In the warm shower, move your arms above your head again in a set of 5. It is hard to just hop out of bed and get your arms up – follow the recipe and you will do great.

Use the momentum you have built to get out and go do something. Walk around the mall, run errands, drive a car. We don't expect you to stop in the mall and start doing your arm exercises. But we do expect you to close your own car door, put on your own seat belt, carry a couple of shopping bags. **Normal movement is essential**.

Expect to run out of energy around mid-day. So plan your day so that you can stop and rest for a while. But after your nap, get up and start moving again.

You will find that the more you move, the better you feel. Treat this like a pulled muscle - yes, you feel it, but it only gets better with movement.

Expect to feel tighter and more swollen at the end of the day. That is normal and temporary.

Expect to begin to feel soreness in the ribs and lower back around the end of day one (1) or day two (2). This is simply fluid moving through the tissue. You will urinate it all out and lose the bloated feeling within five (5) to seven (7) days.

If you feel soreness in your upper back – you are tensing your shoulders into an unnatural position to cause this discomfort. Remember to stretch your shoulders forward and backward – and relax!

MEDICATION SCHEDULE

We expect you to take one tablet of 800 mg Ibuprofen by mouth at breakfast, one tablet at lunch, and one at bedtime. If you need additional relief around dinnertime, you can take 2 tablets of 200 mg Advil.

You can take the Benadryl if you want to before bedtime for the first 5 days only. It is not mandatory.

We expect you to take all of the Ibuprofen we have given you. You may choose to reduce the number per day but we'd like you to take them all.

You should not take aspirin or any products containing aspirin. You should not drink alcohol when taking pain medications. Even when not taking pain medications, you should not drink alcohol for 3 weeks as it causes fluid retention.

Please call the office sometime during your day and let us know how you are doing.

The ONLY DON'T! The only limitation we request is that for two (2) weeks you not engage in strenuous aerobic type exercise that elevates the pulse and blood pressure and can cause internal bleeding. Sex is fine; olympic sex should be delayed for a couple of weeks. When returning to a normal workout or exercise schedule, start slowly, and if comfortable, increase the exercise. If uncomfortable, back off for a couple of days and start again. Common sense is important—you can't harm or cause problems by all normal activities.

FOR MEDICAL QUESTIONS, PLEASE CALL:

Dr. Pelosi III at 201-424-2472

Pelosi Medical Center at 201-858-1800, Monday- Friday, 9:00 am-5:30 pm

After office hours and on weekends, call the number above and leave a message with our answering service. Someone will get back to you right away.

_____ ____/____/____

Patient Signature **Date**

PELOSI MEDICAL CENTER

DVT PATIENT INFORMATION

What is Deep-Vein Thrombosis (DVT)?

DVT occurs when a blood clot forms in one of the large veins, usually in the lower limbs, leading to either partially or completely blocked circulation. The condition may result in health complications, such as a pulmonary embolism (PE) and even death if not diagnosed and treated effectively.

Most common risk factors for DVT:

- Major surgery
- Congestive heart failure or respiratory failure
- Restricted mobility
- Recent injury
- Cancer
- Obesity
- Age over 40 years
- Recent surgery
- Smoking
- Prior family history of venous thromboembolism (VTE)

Signs and Symptoms of DVT:

About half of people with DVT have no symptoms at all. For those who do have symptoms, the following are the most common and can occur in the affected part of the body, typically in the leg or calf region.

- Swelling unrelated to the surgical site,
- Pain or tenderness, unrelated to the surgical site and often worse when standing or walking,
- Redness of the skin,
- Warmth over the affected area.

What is Pulmonary Embolism (PE)?

A pulmonary embolism (PE) is a very serious condition that occurs when a blood clot blocks the artery that carries blood from the heart to the lungs (pulmonary artery). A clot that forms in one part of the body and travels in the bloodstream to another part of the body is called an embolus. PEs often come from the deep leg veins and travel to the lungs through blood circulation.

Signs and Symptoms of PE

- Difficulty breathing;
- Faster than normal heart beat;
- Chest pain or discomfort, which usually worsens with a deep breath or coughing;
- Coughing up blood; or
- Very low blood pressure, lightheadedness, or blacking out.

**** If you develop symptoms of a Pulmonary Embolism, seek emergency medical attention immediately. Dial 911 to be transported to the nearest Emergency Room.***

Patient Signature _____ Date _____

PELOSI MEDICAL CENTER

OFFICE SURGERY CHECKLIST

Procedure (Pt 1) _____ **Surgery Date/Time**: ____/____/____ _____ am/pm

Procedure (Pt 2) _____ **Surgery Date/Time**: ____/____/____ _____ am/pm

Surgeon ☐ MP2 ☐ MP3

#	Task	Date Completed	Initials	Comments
1	Consultation done	___/___/___	_____	_____
2	Signed copy Cosm. Surgery Finan. Agreement given to pt.	___/___/___	_____	_____
3	Blood work drawn. **Must be drawn within 7 days of date of surgery**	___/___/___	_____	**Panel**: CBC, Comp. Met. Panel, PT/PTT, HIV Screening, Hepatitis B & C Screening Repeat PT/PTT if lab panel results in chart. Repeat Panel if date of lab panel results in chart is not within 7 days of scheduled procedure. _____
4	Lab results reviewed by Dr. Pelosi.	___/___/___	_____	_____ _____
5	Medical Clearance Needed? ☐ YES ☐ NO	___/___/___	_____	_____ _____
6	Prescriptions given to patient.	___/___/___	_____	Pt instructions for all Rx's: **Do NOT take day of surgery**

__ Cephalexin	500 mg PO	BID x 8 days (#16)	Begin day before surgery
__ Doxycycline	100 mg PO	BID x 8 days (#16)	Begin day before surgery
__ Flexeril	10 mg PO	TID x 7 days (#21)	2 refills
__ Gabapentin	600 mg PO	TID x 10 days (#30)	
__ Naproxen	500 mg PO	BID x 15 days (#30)	
__ Zofran	8 mg PO	BID as needed (#10)	As needed for nausea

Physician Signature _____

7	Breast implants ordered Breast implants received	___/___/___ ___/___/___	_____ _____	_____ _____
8	Anesthesiologist scheduled	___/___/___	_____	_____
9	Surgery date scheduled & confirmed with patient	___/___/___	_____	_____ _____
10	COVID PCR test performed within 6 days of surgery	___/___/___	_____	
11	Pre-op call made to patient	___/___/___	_____	Med. Asst is responsible for calling patient the day before surgery to reinforce pre-op instructions & answer questions. **Instruct patient to be NPO 8 hrs prior to scheduled procedure time and to bring in a list of current meds and doses.** _____ Allergies: _____ LMP: ____/____/____
12	Lipo touch-ups: Pt advised to bring in old garment	___/___/___	_____	_____ _____
13	**Total Fee: $ _____** Deposit Pd: $ _____	___/___/___	_____	_____ _____
14	Balance Due: $_____ $_____ $_____	___/___/___ ___/___/___ ___/___/___	_____ _____ _____	_____ _____ _____

Pelosi Medical Center

BREAST AUGMENTATION
POST-OPERATIVE INSTRUCTIONS

INSTRUCTIONS

- A responsible adult must drive you home after surgery and help you at home for 1-2 days.
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INCISION CARE

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POST-OP DAY 1

Pelosi Medical Center

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_____ ____/____/____

Patient Signature **Date**

PELOSI MEDICAL CENTER

DVT PATIENT INFORMATION

What is Deep-Vein Thrombosis (DVT)?

DVT occurs when a blood clot forms in one of the large veins, usually in the lower limbs, leading to either partially or completely blocked circulation. The condition may result in health complications, such as a pulmonary embolism (PE) and even death if not diagnosed and treated effectively.

Most common risk factors for DVT:

- Major surgery
- Congestive heart failure or respiratory failure
- Restricted mobility
- Recent injury
- Cancer
- Obesity
- Age over 40 years
- Recent surgery
- Smoking
- Prior family history of venous thromboembolism (VTE)

Signs and Symptoms of DVT:

About half of people with DVT have no symptoms at all. For those who do have symptoms, the following are the most common and can occur in the affected part of the body, typically in the leg or calf region.

- Swelling unrelated to the surgical site,
- Pain or tenderness, unrelated to the surgical site and often worse when standing or walking,
- Redness of the skin,
- Warmth over the affected area.

What is Pulmonary Embolism (PE)?

A pulmonary embolism (PE) is a very serious condition that occurs when a blood clot blocks the artery that carries blood from the heart to the lungs (pulmonary artery). A clot that forms in one part of the body and travels in the bloodstream to another part of the body is called an embolus. PEs often come from the deep leg veins and travel to the lungs through blood circulation.

Signs and Symptoms of PE

- Difficulty breathing;
- Faster than normal heart beat;
- Chest pain or discomfort, which usually worsens with a deep breath or coughing;
- Coughing up blood; or
- Very low blood pressure, lightheadedness, or blacking out.

**** If you develop symptoms of a Pulmonary Embolism, seek emergency medical attention immediately. Dial 911 to be transported to the nearest Emergency Room.***

Patient Signature _____ Date _____

PELOSI MEDICAL CENTER

Medication Reconciliation/ Discharge Summary

Patient Address: _____

ALLERGIES/SENSITIVITIES (Drugs, Materials, Food, or Environmental Factors)	
☐ **No known allergies/sensitivities and other reactions to drugs, materials, food, or environmental factors**	
Allergen	**Reaction**

MEDICATIONS & SUPPLEMENTS						SURGEON to Indicate:		
Medication List: OTC, Herbals, Vitamins & Supplements		DOSE (Strength)	HOW TAKEN?	FREQUENCY (How often taken)	LAST TIME TAKEN	CONTINUE		
						YES	HOLD	NO
1								
2								
3								
4								
5								
6								

Medication History Verified by RN/MA: _____ Date: _____

If a medication is placed on hold or discontinued, Surgeon to indicate patient follow-up instructions below:

_____

_____

IN ADDITION TO THE PRESCRIPTIONS BELOW, THE ABOVE MEDICATIONS SHOULD BE CONTINUED AT HOME UNLESS SPECIFIED BY SURGEON TO HOLD OR DISCONTINUE AS CHECKED ABOVE	
SIGNATURE OF SURGEON REVIEWING MEDICATIONS: (REQUIRED)	DATE:

PRESCRIPTIONS GIVEN TO PATIENT AT DISCHARGE					
Mark with "x"	**Medication Name**	**Dose**	**Route**	**Frequency**	**Reason for Medication**
____	Cephalexin	500 mg	By mouth	2 times a day	Antibiotic
____	Cyclobenzaprine	10 mg	By mouth	3 times a day	As needed, for muscle pain
____	Doxycycline	100 mg	By mouth	2 times a day	Antibiotic
____	Gabapentin	600 mg	By mouth	3 times a day	As needed, for pain
____	Naproxen	500 mg	By mouth	2 times a day	As needed, for pain
____	Ondansetron	8 mg	By mouth	2 times a day	As needed, for nausea
____					

Procedure(s) Performed: _____

Medications administered during this visit: ☐ Ceftriaxone ☐ Cephalexin ☐ Clindamycin ☐ Diazepam ☐ Diphenhydramine ☐ Diprivan ☐ Doxycycline ☐ Epinephrine ☐ Fentanyl ☐ Glycopyrrolate ☐ Lidocaine ☐ Metoclopramide ☐ Midazolam ☐ Ondansetron ☐ Oxycodone ☐ Sodium Bicarbonate ☐ Tranexamic Acid ☐ Other _____

Information provided to: ☐ Patient _____ ☐ Other _____
(*patient signature*) (*name of person*)

Discharge Physician/RN Signature: _____ Date: _____ Time: _____

PELOSI MEDICAL CENTER

OFFICE SURGERY PRE-OP HISTORY & PHYSICAL EXAM

CHIEF CONCERN / REQUEST:

PERTINENT PAST MEDICAL & SURGICAL HISTORY AND REVIEW OF SYSTEMS:

PHYSICAL EXAMINATION:

Height _____ Weight _____ lbs Pre-op Exam Vital Signs: BP_____ T _____ HR _____ RESP _____

WNL	ABN		COMMENTS
D	D	General appearance	
D	D	Mental Status	
D	D	Neurological	
D	D	Cardiovascular	
D	D	Lungs	
D	D	Abdomen	
D	D	Genitourinary	
D	D	Liver	
D	D	Extremities	
D	D	Integument	
D	D	Other	

CURRENT MEDICATION	DOSAGE

CURRENT MEDICATION	DOSAGE

ALLERGIES/SENSITIVITIES			
☐ No known allergies/sensitivities and other reactions to drugs, materials, food, or environmental factors			
Allergen/Sensitivity	Type of Reaction	Allergen/Sensitivity	Type of Reaction

Adverse Reactions to Drugs: ☐ No ☐ Yes _____

PROVISIONAL DIAGNOSIS:

LETTER OF MEDICAL CLEARANCE NEEDED?___ YES ___ NO

PHYSICIAN SIGNATURE _____ **DATE** ____/____/____

Pelosi Medical Center

VTE RISK FACTOR ASSESSMENT

Date: ___/___/___

Age: _____ Wt (lbs): _____ BMI: _____

Sex: _____ Ht (in): _____

CHOOSE ALL THAT APPLY

Add **1 Point** for Each Risk Factor

___ Age 41-60 years
___ Minor surgery (< 45 min) planned
___ Past major surgery within last month
___ Visible varicose veins
___ History of inflammatory bowel disease
___ Swollen legs (current)
___ Overweight or obese (BMI > 30)
___ Serious infection (< 1 month)
___ Lung disease (e.g., emphysema, COPD)
___ Heart attack
___ Congestive heart failure
___ Other risk factors _____

Add **2 Points** for Each Risk Factor

___ Age 61-74 years
___ Planned major surgery (> 45 minutes)
___ Previous malignancy (excl skin cancer, but not melanoma)
___ Central venous access within last month
___ Non-removable plaster cast that kept pt from moving leg within last month
___ Confined to a bed for 72 hrs or more

Add **3 Points** for Each Risk Factor

___ Age 75 years or over
___ History of blood clots – either DVT or PE
___ Family history of blood clots (thrombosis)
___ Personal or family history of positive blood test indicating increased risk of blood clotting

For Women Only: Add **1 Point** for Each Risk Factor

___ Current use of oral contraceptives or hormone replacement therapy
___ Pregnancy or postpartum within last month
___ History of unexplained stillborn infant, recurrent spontaneous abortion (> 3), premature birth with toxemia or growth- restricted infant

Add **5 Points** Each Risk Factor that **applies now or within the past month**

___ Elective hip or knee joint replacement surgery
___ Broken hip, pelvis, or leg
___ Serious trauma e.g., multiple broken bones due to a fall or car accident
___ Spinal cord injury resulting in paralysis
___ Experienced a stroke

TOTAL RISK FACTOR SCORE _____

Score	Risk Level	Prophylaxis for Surgical Patients
0-2	Low	• Early ambulation
3-8	Increasing	• Apply antiembolism stockings and intermittent pneumatic compression device • Flex patient's knees to approximately 5° by placing a pillow underneath them • Stage multiple procedures • Provide patient with DTV Patient Information Sheet • Instruct patients who are taking oral contraceptives or hormone replacement therapy to discontinue taking these medications 1 week prior to surgery.
> 8	18.3%	• Not a candidate for office-based surgery

PELOSI MEDICAL CENTER

PHYSICIAN PERIOPERATIVE ORDERS

PRE-OPERATIVE

Enter 'x' next to medication & circle prescribing dose

☐ DiphenHYDRAMINE	**25** / **50** mg PO x 1	☐ CefTRIAXone	**1** gm (< 79 kg) **2** gm (≥ 79 kg) **3** gm (≥ 120 kg) IV Piggyback x 1
☐ Diazepam	**10** / **20** mg PO x 1	☐ Clindamycin	**600** mg (< 70 kg) **900** mg (≥ 70 kg) IV Piggyback x 1
☐ FentaNYL	**50** / **75** / **100** mcg IM x 1	☐ Cephalexin	**500** / **1000** mg PO x 1
☐ Midazolam	**2** / **4** / **6** / **8** mg IM x 1	☐ Doxycycline	**100** / **200** mg PO x 1
☐ OxyCODONE	**5/325** / **10/650** mg PO x 1		

___ Apply ECG, NIBP, & Pulse Oximeter monitors during procedure

___ Urine pregnancy test (n/a if female > 55 yrs old or if post-hysterectomy)

___ Apply Norm-o-temp heating pad. Set temperature to_____° F (no greater than 104° F)

Additional pre-operative orders: _____

_____

INTRA-OPERATIVE

___ Tumescent Anesthetic Solution - Use 1000ml bags of 0.9% NaCl

Bag #	Lidocaine (mg)	Epinephrine (mg)	Sodium Bicarbonate 8.4% (ml)	Tranexamic Acid (mg)
1			10	
2			10	
3			10	
4			10	
5			10	

Bag #	Lidocaine (mg)	Epinephrine (mg)	Sodium Bicarbonate 8.4% (ml)
6			10
7			10
8			10
9			10
10			10

___ Apply thromboembolic stockings and Intermittent Pneumatic Compression Device set at **40mm Hg**

Additional intra-operative orders: _____

_____

POST-OPERATIVE

___ Discontinue IV when discharge criteria are met

___ Remove Foley catheter

Additional post-operative orders:

_____

PHYSICIAN SIGNATURE_____ **DATE/TIME:** ____/____/____ ____:___

ADDITIONAL ORDERS:

_____

_____

_____

PHYSICIAN SIGNATURE_____ **DATE/TIME:** ____/____/____ ____:___

Pelosi Medical Center

Breast Augmentation Authorization and Consent

Date of Consult: ____/____/____ Height: _____ft. _____in. Weight: _____lbs.

Current Bra Size: _____ Desired Implant Location (Check One): ☐ Subpectoral ☐ Subglandular

I authorize Marco A. Pelosi II/III, MD, associate surgeons, and/or such assistants as may be selected and supervised by them to perform bilateral breast augmentation surgery (bilateral augmentation mammoplasty) with saline/silicone implants placed either over the chest muscles (subglandular placement), or under the chest muscles (subpectoral placement), through skin incisions located under the breasts (inframammary skin incisions), axillary, areolar, or belly button. Surgery will be performed with a combination of local anesthesia administered by your surgeon and intravenous sedation administered by an anesthesiologist.

The nature and effects of the operation, the risks, ramifications, complications involved, as well as alternative methods of treatment and their likely results, have been fully explained to me by the Doctor and/or his associates, and all of my questions have been answered to my satisfaction. I acknowledge that no guarantee has been made as to the results. I know that breast augmentation surgery should not be done if a woman is pregnant; I have no reason to suspect that I might be pregnant.

I have read, understood and initialed all of the information supplied to me in the attached forms entitled *Breast Augmentation Surgery Risks* and *Breast Augmentation: Frequently Asked Questions*. I have had sufficient opportunity to discuss these materials with the Doctor and/or his associates. I believe that I have adequate knowledge upon which to base an informed consent to the proposed treatment.

I agree to avoid activities which require much raising of the arms above the level of the head for ten (10) days after surgery. I agree not to drive for 72 hours after surgery. I agree to avoid all strenuous arm movements and activities for the first six (6) weeks after surgery. I agree to stop smoking for two (2) weeks after surgery.

I agree to allow the surgeon, associate surgeon, and staff to photograph or video me before, during and after the operation. The photographs, videos, tapes and digital media shall be the property of the surgeon and may be used for teaching, marketing, publication or scientific research purposes. If my surgery has been scheduled during a training course held by Drs. Marco A. Pelosi, I agree to allow physicians attending the training course to observe and/or participate in my surgery under the direct supervision of Drs. Marco A. Pelosi. I agree to routine pre-operative blood tests, including a test for HIV (AIDS). I request local anesthesia and any medications deemed necessary by the surgeon.

Breast augmentation surgery is associated with certain expected temporary side effects including soreness, inflammation, bruising, swelling, numbness, and minor irregularity of the skin. Some of these effects can take several months to resolve. Scars, pigment changes, or an irregularity that persists for more than six months may or may not be correctable by a second procedure. Any surgery may involve risks of more serious and unexpected problems including infection, pain, delayed wound healing, scarring, blood clots, excessive bleeding, hematoma, seroma (temporary accumulation of fluid under the skin), injury to other tissues, allergic or toxic reactions to drugs, and even death.

Breast augmentation surgery is associated with certain specific risks and complications which include dissatisfaction with the appearance of the implants, incorrect implant size, visible scar location, asymmetry (unequal breast size or shape), sagging or drooping over time (ptosis), breakage through the skin, wrinkling and rippling of the implant shell, capsular contracture (scarring around the implant shell which can squeeze the implant and lead to excessive firmness and possible pain), implant rupture, implant deflation over time (due to normal wear, injury, valve malfunction, breast manipulation, mammograms, or unknown reasons), numbness and/or sensory changes (temporary or permanent, which can interfere with comfort, sexuality and nursing), pain, infection (which may require removal of the implant if it is not controlled with antibiotics), hematoma, scars (which may become thickened, red, hypertrophic or keloid), interference with mammography (which may "hide" suspicious lesions), calcium deposits (which are benign, but may be confused on an X-ray with suspicious calcium deposits and require a biopsy), alteration in breast feeding, spontaneous temporary lactation after surgery. Implants will not last forever. The FDA currently estimates that implants will last about ten (10) years. Any of these problems noted above may require additional surgery, hospitalization, and time away from work. If this occurs, there will be additional costs for surgical fees, supplies, anesthesia, etc., depending upon the required operation. Complications of cosmetic surgery generally will not be covered by medical insurance.

Pelosi Medical Center

Breast Augmentation Authorization and Consent

Please initial each statement in the space provided to indicate that you understand that statement.

_____**What are the benefits of breast augmentation with implants?** This operation is performed to enhance or restore the size and shape of a woman's breasts. Breasts may be small because of lack of development or changes following pregnancy, weight loss or congenital abnormalities. Sometimes a woman's breasts are very asymmetric. This operation can improve a woman's self esteem and quality of life. Studies have shown over 90% of women are satisfied with their results. Currently, saline implants (silastic bags filled with salt water) are placed either behind the pectoral muscle and breast tissue or in front of the muscle. This is done through an incision 1 ½" to 2" long placed either under the breast, around the areola, or in the armpit.

_____**What do breasts look like after augmentation mammoplasty?** Saline-filled prostheses are the best means now available to enlarge the breasts by surgery. However, the prospective patient should know that the final appearance, shape and texture are not exactly the same as normal breasts. The surgically enlarged breasts do not move in the same way as normal breasts. They tend to be more firm. The contours are usually somewhat different than normal breasts. In some patients, these discrepancies may be rather noticeable. Although every effort is made to place the implants symmetrically, complete symmetry is rarely achieved. Immediately after surgery, the breasts may appear swollen and firmer; the final shape and size is seen after several weeks. Please note that silicone gel implants are no longer available for elective new breast augmentations because of FDA restrictions.

_____**Are the prostheses safe? Can they cause cancer?** To the best of our present knowledge, these prostheses are made of non-reactive, safe material. No one has had them in place for more than about 25 years at this time. Thus, there is no way to say positively that they won't cause trouble 20 years from now, but it is unlikely. The incidence of cancer in augmented breasts is the same as in normal breasts, actually less in some studies. Additionally, the incidence of collagen vascular disease is the same or less in studies of women with breast implants.

_____**What kind of anesthetic is used?** A local anesthetic with sedation is commonly used when the implant is placed over the pectoral muscle. A local anesthetic either alone or in combination with sedatives, or general anesthesia, is used when the implant is placed under the pectoral muscle.

_____**What are my limitations in activity post-operatively?** You should plan to avoid activities which require much raising of the arms above the level of the head for 10 days after surgery. With great care, you can drive about 3 days after surgery. Patients can usually return to work in a few days unless their occupation requires particularly strenuous movements and lifting. In such cases, 2-3 weeks should be allowed. Intense physical activity should be avoided for six (6) weeks after surgery.

_____ **COSMETIC COMPLICATIONS:** You may not be satisfied with the appearance of your implant(s). Incorrect implant size, inappropriate scar location or appearance, and misplacement of implants may interfere with a satisfactory appearance. Asymmetry (unequal breast size or shape) may occur. The implanted breast may sag or droop (ptosis) over time, much like a natural breast. Very rarely the implant may change position or break through the skin, particularly if you have very thin breast tissue covering it. This is more common with saline implant(s).

____ **BLEEDING:** When blood collects beneath the skin, it causes excessive discoloration. Sometimes lumps which last many months may occur. If blood collection is discovered, it is usually removed by taking out a few stitches and squeezing the clot out, or inserting a needle and aspirating it. If bleeding continues, it is sometimes necessary to return to the operating room to stitch the bleeding vessels. This risk increases in people who take aspirin or who bruise easily. Let your doctor know if this is the case. Do not use aspirin or aspirin-containing products for two weeks before and two weeks after surgery. (See Medication Precautions for Surgery Patients sheet).

_____ **WRINKLING AND RIPPLING:** Some wrinkling of the implant shell is normal and expected. If your breast tissue is very thin, these wrinkles can show up as visible ripples, especially when you lean forward without wearing a brassiere. The wrinkling can also produce little corners on the implants that can sometimes be felt with your finger if the breast tissue is very thin.

_____ **CAPSULAR CONTRACTURE:** The scar tissue that forms around the implant can tighten and squeeze the implant as a natural response to a foreign object implanted in the body. This firmness can range from slight to very firm. The firmest ones can cause varying degrees of discomfort or pain. Capsular contracture can occur on one breast or both. Implants under the muscle may result in less contracture.

_____ **RUPTURE/DEFLATION:** Breast implants may not last a lifetime. The silastic shell can break due to normal wear over time, injury, valve malfunction, breast manipulation (mammograms), or unknown reasons. The usual sign is loss of breast size over days or weeks. The saline (salt water) will be absorbed by the body without any harm. Surgical replacement will be needed to restore the breast size. Replacement will involve additional costs.

_____ **NUMBNESS:** Sensory changes are expected to some degree immediately after surgery but loss of nipple and breast sensation may be permanent. Increased sensitivity is less common but does occur. These changes can interfere with comfort, sexuality and nursing (lactation).

Pelosi Medical Center

Breast Augmentation Authorization and Consent

_____ **PAIN:** Can be related to the surgery itself or a later response to problems such as tight capsule formation.

_____ **INFECTION:** May require removal of the implant if it is not controlled with antibiotics. Consideration should be given to taking prophylactic antibiotics with dental work or other surgeries. If an implant is removed, replacement may be delayed for three months.

_____ **HEMATOMA:** May require surgery to remove the collection of blood. Sudden swelling of the breast after surgery should be immediately reported to the doctor.

_____ **SCARS:** Generally do well with all breast incisions. However, healing is unpredictable and occasionally patients may form thickened or red hypertrophic/keloid scars. Additional surgery may be required. Wound healing complications are higher is smokers therefore, you must stop smoking at lease 2 weeks before and 2 weeks following surgery.

_____ **INTERFERENCE WITH MAMMOGRAPHY:** An implant can interfere with the detection of early breast cancer because it may "hide" suspicious lesions in the breast during an X-ray exam. It is especially important for women who are at high risk of developing breast cancer to consider this before having implants. Additional views are required for routine mammography in patients with implants. Mammography is more effective with implants under the muscle.

_____ **CALCIUM DEPOSITS:** Can develop in the breast tissue at any time after surgery. These are benign but may be confused on an X-ray with breast cancer calcium deposits and require a biopsy.

_____ **ALTERATION IN BREAST FEEDING:** For women who have not had children, this surgery may alter your ability to nurture children in the future. Spontaneous lactation may occur after this surgery but is usually self-limited.

_____ **LIFETIME OF IMPLANT:** Implants will not last forever. The FDA currently estimates implants will last about 10 years. This is an estimate. The FDA has not reviewed all the data about saline implants (1994).

_____ **UNKNOWN RISKS:** In addition to these known risks, there are unanswered questions about saline-filled breast implants. For example, questions have been raised about whether these devices might cause autoimmune diseases such as lupus, scleroderma and rheumatoid arthritis in some women, or whether they might increase the risk of cancer. There is no scientific evidence at present that women with either silicone gel-filled or saline-filled breast implants have increased risk of these diseases, but the possibility cannot be ruled out.

Patient Signature	Date	Witness Signature	Date	Surgeon Signature	Date
_____	__/__/__	_____	__/__/__	_____	__/__/__

Pelosi Medical Center

ALLERGAN NATRELLE SALINE BREAST IMPLANTS PATIENT DECISION CHECKLIST

WARNING:

- 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.

The sale and distribution of this device is restricted to users and/or 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.

To the patient considering breast implants filled with saline or silicone gel intended for breast augmentation or breast reconstruction:

The review and understanding of this document is a critical step in making the decision whether you should choose breast implant surgery. You should learn about breast implants and then carefully consider the benefits and risks associated with breast implants and breast implant surgery before you make that decision. This form lists important risks, including those known or reported to be associated with the use of the device based on information from clinical trials, scientific literature, and reports from patients who have undergone device placement.

This Patient Decision Checklist is intended to supplement the additional patient information documents that should be provided to you by your physician. You should receive patient information documents that include important information about your specific breast implant, as well as a boxed warning and Patient Decision Checklist. After reviewing the information in the patient information documents for the specific implant that will be used, please read and discuss the items in this checklist carefully in consultation with your physician. You should place your initials in the location provided next to each item to indicate that you have read and understood the item. Your full signature at the end of this document confirms that you have read the materials and that your physician has answered all questions to your satisfaction.

Considerations for a Candidate for Successful Breast Implantation

I understand that I am not a candidate for breast implants if any of the following situations applies to me:

- I have an active infection anywhere in my body;
- I have an existing cancer or pre-cancer of my breast tissue that has not been adequately treated; or
- I am pregnant or nursing.

I understand that if I have any of the following conditions, I may be at a higher risk for a poor surgical outcome:

- Medical condition that affects my body's ability to heal (e.g., diabetes, connective tissue disorder);
- Active smoker or a former smoker;
- Currently taking drugs that weaken the body's natural resistance to disease, such as steroids and chemotherapy drugs (e.g., prednisone, tacrolimus, sirolimus, mycophenolate, azathioprine, cyclosporine, methotrexate, chlorambucil, leflunomide, or cyclophosphamide);
- History of chemotherapy or planned chemotherapy following breast implant placement;
- History of radiation therapy or planned radiation following breast implant placement;
- Conditions that interfere with wound healing or blood clotting (e.g., hemophilia, von Willebrand disease, factor V Leiden, hyperhomocysteinemia, protein C deficiency, antithrombin III deficiency, or systemic lupus erythematosus); or
- Reduced blood supply to the breast tissue.

Pelosi Medical Center

ALLERGAN NATRELLE SALINE BREAST IMPLANTS

PATIENT DECISION CHECKLIST

I understand the following conditions have not been adequately studied to determine whether the conditions put me at higher risk:

- Autoimmune disease (e.g., Hashimoto's, Lupus, Rheumatoid Arthritis) or family history of autoimmune disease (breast implant premarket clinical studies have not evaluated the safety of breast implants in patients with autoimmune disease);
- Clinical diagnosis of depression or other mental health disorder (including body dysmorphic disorder or eating disorder); or
- Have other products permanently implanted in the breast.

Patient Initials: _____

Risks of Breast Implant Surgery

I understand that there are risks of undergoing breast implant surgery. I understand that risks of undergoing breast implant surgery may include:

- breast pain (reported in up to 33% of patients[1]),
- skin or nipple areola sensitivity changes or loss (loss of nipple sensation reported in up to 18.1% of patients[2], intense nipple sensation reported in up to 9.8% of patients[2] and intense skin sensation reported in up to 7.6% of patients[2]),
- asymmetry (reported in up to 39.0% of patients[2]),
- impact of aging or weight change on size and shape of breast (may occur in saline procedures but specific rates are not publicly available in the Allergan clinical studies),
- infection requiring possible removal of implant (reported in up to 6.0% of patients[2]),
- swelling (may occur in saline procedures but specific rates are not publicly available in the Allergan saline clinical studies)
- scarring (scarring complications reported in up to 6.5% of patients[2]),
- fluid collections (seroma) (reported in up to 3.9% of patients[2]),
- hematoma (reported in up to 1.7% of patients[2]),
- tissue death of breast skin or nipple (tissue/skin necrosis reported in up to 3.6% of patients[2]),
- inability to breast feed (may occur but specific rates are not publicly available in the Allergan clinical studies),
- complications of anesthesia (may occur but specific rates are not publicly available in the Allergan clinical studies),
- bleeding (may occur but specific rates are not publicly available in the Allergan clinical studies)
- chronic pain (may occur but specific rates are not publicly available in the Allergan clinical studies)
- damage to surrounding tissue, such as muscle, nerves, and blood vessels (may occur but specific rates are not publicly available in the Allergan clinical studies)
- impact on imaging of breast tissue (may occur but specific rates are not publicly available in the Allergan clinical studies).

My physician has discussed these risks and has provided me with the patient information documents (including the boxed warning) with information on the types of risks that are possible and expected rates of occurrence.

My physician has discussed the potential use of other implanted products during my breast implant surgery. My physician has also discussed the risks and benefits of using these implanted products and their planned surgical approach.

Patient Initials: _____

[1] Based on the largest complication rate reported in the A95/R95 Clinical Study through 10 years of follow-up. See Sections 7.3 and 8.3 of the *Natrelle*® Saline Filled Breast Implants Patient Document

[2] Based on the largest complication rate reported in the A95/R95 Clinical Study through 5 years of follow-up. See Sections 7.3 and 8.3 of the *Natrelle*® Saline Filled Breast Implants Patient Document

Risk of Cancer - Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

I understand that breast implants are associated with the development of a type of cancer of the immune system called Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Information regarding the number of medical device reports of BIA-ALCL can be found on FDA's website.[3]

As of July 2019, literature reports various estimates for the incidence of BIA-ALCL. These estimated incidence rates range from a high of 1 per 3,817 patients to 1 in 30,000. (Clemens et al, 2017, Loch-Wilkinson et al, 2017, De Boer et al, 2018).

I have received information regarding the overall incidence rates of BIA-ALCL and the rates as they pertain to my specific breast implant.

I understand that this cancer has been reported more frequently for textured breast implants, but patients with smooth surfaced implants have also been diagnosed.

I understand that patients with breast implants have a risk of developing BIA-ALCL within the scar tissue and fluid surrounding the breast implant.

I understand that BIA-ALCL typically takes several years to develop after implantation, but cases have been reported as early as within one year. Typical symptoms to be aware of may include: breast tightness, pain, lumps, or swelling of the breast months or years after I receive my implants.

I understand that treatment for BIA-ALCL involves an operation to remove the implants and the surrounding scar tissue capsule. Based on the stage of the cancer at diagnosis, some patients have required chemotherapy or radiation. While BIA-ALCL typically responds well to therapy, some patients have died from BIA-ALCL. Diagnosis and treatment may be at my own expense and is not always covered by insurance.

Patient Initials: _____

Systemic Symptoms

I understand that some patients who have received breast implants have reported a variety of systemic symptoms including joint pain, fatigue, rash, memory loss, and "brain fog" that some patients have called breast implant illness. While the causes of these symptoms are unclear, some patients have reported relief of these symptoms with removal of their implants and surrounding scar capsule; however, not all patients may experience improvement in their symptoms. Researchers are working to better understand the possible link between breast implants and these symptoms.

I also understand that some patients with breast implants have reported health problems in their children after birth or breastfeeding. A causal link has not been established between breast implants and these reported health problems in children and more research is needed. I understand that breast implants and breast surgery may interfere with my ability to successfully breastfeed.

Patient Initials: _____

[3] See "Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma," available at https://www.fda.gov/ medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma.

Breast-Implant Specific Risks

I understand that a breast implant is NOT a lifetime device and the longer I have my implants, the more likely I am to experience a complication and the more likely I am to need a reoperation requiring the replacement or removal of my breast implant. As many as 20.2% of women who receive Allergan saline breast implants for augmentation had their implants removed within 10 years, but my implants may last for a shorter or longer period of time. (The percentage reported is from the 10-year A95/R95 Clinical Study for Natrelle Saline-filled breast implants.)

I understand that my breast implant may rupture or leak at any time, and that the longer I have my implants, the more likely I am to experience a complication such as rupture. I understand that gel bleed (small quantities

of gel diffusing from the implant shell) of silicone gel-filled implants may occur. I understand that if I have a saline-filled implant, my breast may deflate in appearance if there is a rupture or leakage of the saline.

I understand that if I have a silicone gel-filled breast implant, I or the physician may not be able to tell on physical exam whether my implant has ruptured or is leaking silicone gel. Because rupture or leakage of silicone gel-filled breast implants is difficult to detect, I understand that periodic imaging evaluation is recommended for screening of silicone gel-filled breast implant rupture. It is recommended that I have periodic imaging of my silicone gel-filled breast implants to screen for implant rupture regardless of whether my implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on my medical history or circumstances (i.e., screening mammography for breast cancer).

Even if I have no symptoms, I should have regular imaging evaluations as described in the "Recommended Follow-Up" section below. These imaging evaluations may not detect all ruptures or leaks, and the expense may not be covered by my medical insurance.

I understand that there are rare case reports of silicone migrating from breast implants into tissues (e.g., chest wall, lymph nodes under the arm) and organs (e.g., liver, lungs). It may not be possible to remove migrated silicone.

I understand that all breast implants can affect mammography and breast exams, which could potentially delay the diagnosis of breast cancer. Mammography can also cause the breast implant to rupture or leak. I should tell the mammography technician if I have breast implants.

I understand that the long-term risks of breast implants may include:

- painful or tightening of scar tissue (capsule) around my implant (capsular contracture III/IV) (reported in up to 51.7% of patients[1]),
- rupture or leaking of the implant (implant deflation reported in up to 22.5% of patients[1]),
- wrinkling of the implant (wrinkling/rippling reported in up to 24.6% of patients[2]),
- visibility of the implant edges (implant palpability/visibility reported in up to 27.1% of patients[1]),
- shifting of the implant (implant malposition reported in up to 16.9% of patients[2]), or
- reoperation (reported in up to 54.6% of patients[1]).

I understand that I will receive a Device Identification Card after my surgery that has information on each of my specific implants. I understand that it is important for me to keep each card in case, at some time in the future, I or my physician need to know what kind of implant I received many years later.

I understand that breast implant manufacturing requires the use of chemicals and heavy metals. I understand that most of these chemicals stay inside the shell of the implant. Small quantities may diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking.

A list of the components, chemicals, and heavy metals is available in the section entitled, **"*NATRELLE*® Silicone-Filled/Saline-Filled Breast Implant Device Materials"** of the patient information document.

Patient Initials: _____

Recommended Follow-up

For silicone-gel filled implants, even if I have no symptoms, I should have my first ultrasound or MRI at 5-6 years after my initial implant surgery and then every 2-3 years thereafter. If I have symptoms or uncertain ultrasound results for breast implant rupture, an MRI is recommended.

I understand that for as long as I have my breast implant(s), I will need routine and regular follow-up with my physician, for examination of my breast implant(s) as well as to discuss any updates regarding breast implant issues.

National Breast Implant Registry (NBIR): I understand and have discussed with my physician that there is a National Breast Implant Registry where information regarding my health and breast implant information can be

entered. The NBIR may help understand the long-term safety and performance of breast implants.

Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma (ALCL) etiology and Epidemiology (PROFILE): I understand and have discussed with my physician that there is a registry (PROFILE) where information is collected to better understand BIA-ALCL in patients with breast implants.

Patient Initials: _____

Questions for My Physician

I have had the opportunity to ask my physician questions about his or her experience, medical degree, specialty of training, and credentials. I understand that breast implants have associated procedural risks and should only be used by physicians who are appropriately trained.

Patient Initials: _____

Options Following Mastectomy

I understand that breast reconstruction is an elective procedure, which I can choose to do or not.

I understand that I may choose not to have breast reconstruction ("going flat") and may choose to use an external prosthesis in my bra to look like I have a breast when wearing clothes.

I understand the surgical options for breast reconstruction, including the use of a breast implant and the use of my own tissue ("autologous reconstruction").

I understand that if my breast implants are ever removed, I may be left with dimpling, chest wall concavity, puckering, or sagging of my breasts or skin.

I understand that more surgeries may be necessary in the future due to complications or to remove or replace the breast implants.

I have discussed all of the options for breast reconstruction with my surgeon, including whether I am a candidate and the benefits and risks of each, and I believe that breast reconstruction with a breast implant is the best option for me.

Patient Initials: _____

Breast Augmentation Options

I understand that breast augmentation is an elective procedure to increase the size of my breasts.

I understand that breast augmentation may result in permanent changes to my breast tissue and if my implants are ever removed, I may be left with an unsatisfactory appearance,
changes to the size and shape of my breasts, including but not limited to dimpling, chest-wall concavity, puckering, sagging, or different incision size or location.

If I am an augmentation patient, any additional surgeries or medical procedures will likely be at my own expense.

Patient Initials: _____

Pelosi Medical Center

ALLERGAN NATRELLE SALINE BREAST IMPLANTS

PATIENT DECISION CHECKLIST

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the patient information documents for the specific implant that will be used during my surgery and that I have had time to discuss the information in it and on this document with my physician. I have had the opportunity to ask questions and understand the benefits and risks of breast implants for me, given my specific health conditions. I have considered alternatives to breast implants, including reconstruction without breast implants, no reconstruction/augmentation, and their respective benefits and risks.

_____ _____

Patient Signature **Date**

Physician: I acknowledge that I have discussed the benefits and risks of breast implants as described elsewhere in the patient information documents and in this checklist. I have also explained the benefits and risks of the alternatives. I have encouraged the patient to ask questions, and I have addressed all questions.

_____ _____

Physician Signature **Date**

SCAN TO REVIEW *NATRELLE*® Saline-Filled Breast Implant Full Brochure (Augmentation and Reconstruction)

Pelosi Medical Center

CIGARETTE SMOKING ATTESTATION

All procedures in cosmetic surgery are performed to improve form and, in some cases, function. Our goal as cosmetic surgeons is to achieve improvement with minimal scarring. Unfortunately, smoking and secondary smoke affect wound healing in a potentially devastating way. Please be honest with us about your exposure to smoke so we can take good care of you and prevent problems and complications with your procedure.

Any exposure to smoke either directly or indirectly can result in poor wound healing, delayed wound healing, skin loss requiring skin grafting, increased risk of wound infection, and loss of skin and deeper tissues, all due to decreased blood supply to those areas. The reduced blood flow to skin wound edges can cause skin to break down and scab. This will negatively affect the quality and nature of the scar (there is an increased risk of hypertrophic or keloid scarring). This is true for any surgical procedures requiring incisions (even skin lesion removal and liposuction).

The following is a partial list of cosmetic procedures and the impact that smoking or inhaling second-hand smoke may have on wound healing. It is not intended to be a complete list of procedures or all possible complications. Because of these potential complications, the immediate stopping of smoking at least 4 weeks before the surgeries and postoperative abstinence for life, or for at least 4-6 weeks postoperative, is advised.

Breast Implants (Reconstruction, Tissue Expanders, and Augmentation): There is an increased risk of delayed wound healing, capsular contracture, and implant infection with the possibility of extrusion.

Breast Reduction and Breast Lift (Mastopexy): There can be delayed wound healing resulting in unsightly scarring and skin loss and potential nipple loss requiring skin graft. In all cases of patients who smoke or are exposed to smoke, wounds do not heal in the normal length of time. Wound healing can be prolonged as long as 3-4 months.

Abdominoplasty: Smoking or exposure to smoke will decrease the ability of the skin to heal properly resulting in unsightly scarring, higher risk for infection, and skin loss sometimes requiring a skin graft. Slow wound healing (months instead of weeks), skin loss resulting in scabbing and prolonged need for dressing changes, and infection (usually requiring antibiotics and sometimes another surgery to drain the infection) are all complications that can occur if you smoke or are exposed to second-hand smoke. If you have either stopped smoking very recently or have been unable to stop completely, you must accept these risks if you wish to proceed with surgery.

Liposuction and Fat Transfer: There is an associated increased risk of skin complications with *liposuction* (postoperative pain, inflammation, infection, bruising, swelling, loss of sensation in the skin, skin irregularities, skin necrosis, fat embolism, seroma, scarring, changes in skin coloration, etc.) and *fat transfer* (infection, fat necrosis, skin irregularities, and decrease in the retention of injected fat, etc.) in smokers.

Patient Initials

_____ I have read and understand the Patient Information on Cigarette Smoking and Cosmetic Surgery and I have had all of my questions regarding this form answered to my full satisfaction by my surgeon prior to my operation today.

IF YOU HAVE NEVER SMOKED CIGARETTES:

_____ I attest that I have never smoked cigarettes.

IF YOU ARE A PREVIOUS OR CURRENT SMOKER:

_____ I attest that I (have/have not) _____ quit cigarette smoking or refrained from cigarette smoking for at least four (4) weeks prior to my surgery today.

_____ I have been advised by my surgeon to refrain from cigarette smoking for at least six (6) weeks after my surgery today and preferably to quit smoking permanently.

Print Name: _____ **Signature:** _____ **Date:** ____/____/____

PELOSI MEDICAL CENTER

ANESTHESIA CONSENT

TO THE PATIENT: *You have the right, as a patient, to be informed about your condition and the recommended anesthesia/analgesia to be used so that you may make the decision whether or not to receive the anesthesia/analgesia after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the anesthesia/analgesia.*

I voluntarily request that anesthesia care (analgesia) as indicated below be administered to me (the patient). I understand it will be administered by an anesthesia provider and/or other practitioner, and such other health care providers as necessary. Perioperative means the period shortly before, during and shortly after the procedure.

I understand that anesthesia/analgesia involves additional risks and hazards but I request the use of anesthetics/analgesia for the relief and protection from pain during the planned and additional procedures. I realize the type of anesthesia/analgesia may have to be changed possibly without explanation to me.

I understand that serious, but rare, complications can occur with all anesthetic/analgesic methods. Some of these risks are breathing and heart problems, drug reactions, nerve damage, cardiac arrest, brain damage, paralysis, or death.

I also understand that other complications may occur. Those complications include but are not limited to:

Check planned anesthesia/analgesia method(s) and have the patient/other legally responsible person initial.

☐ _____ LOCAL ANESTHESIA/ANALGESIA and/or TUMESCENT ANESTHESIA - drowsiness, allergic reaction, nausea and vomiting, nervousness, apprehension, euphoria, confusion, dizziness, blurred or double vision, generalized muscle twitching, seizures, respiratory depression, bradycardia, peripheral vasodilation, hypotension, depressed myocardial contractility, depressed cardiac conduction.

☐ _____ REGIONAL BLOCK ANESTHESIA/ANALGESIA - nerve damage; persistent pain; bleeding/hematoma; infection; medical necessity to convert to general anesthesia; brain damage.

☐ _____ MONITORED ANESTHESIA CARE (MAC) or SEDATION/ANALGESIA - memory dysfunction/memory loss; medical necessity to convert to general anesthesia; permanent organ damage; brain damage, and the need to be transferred to a hospital.

Additional comments/risks:

_____

_____

I understand that no promises have been made to me as to the result of anesthesia/analgesia methods.

I have been given an opportunity to ask questions about my anesthesia/analgesia methods, the procedures to be used, the risks and hazards involved, and alternative forms of anesthesia/analgesia. I believe that I have sufficient information to give this informed consent.

_____	__/__/__	_____	__/__/__	_____	__/___/___
Patient Signature	Date	Witness Signature	Date	Surgeon Signature	Date

PELOSI MEDICAL CENTER

ANESTHESIA PERIOPERATIVE EVALUATION

Date	Time	NPO Since	Ht	Wt	ALLERGIES

MEDICAL HISTORY	MEDICATION RECONCILIATION FORM REVIEWED ☐	AIRWAY
COVID-19 PCR test result present ☐ COVID-19 screening done ☐		
SURGICAL HISTORY	**MONITOR TESTED & ANESTHESIA CART CHECKED ☐**	**TEETH**
ANESTHESIA HISTORY		

SYSTEM REVIEW		HISTORY	EVALUATION	PHYSICAL
	WNL Cardiovascular			
	WNL Pulmonary			
	WNL GU/GYN			
	WNL Gastrointestinal			
	WNL Hematologic			
	WNL Endocrine/Metabolic			
	WNL Musculoskeletal			
	WNL Neurologic			
	WNL CXR	WNL ECG	WNL BMP	Hbg _____ Hct _____

PLAN OF CARE

ASA Classification: I II III IV ☐ Local ☐ Conscious Sedation

☐ Anesthesia risks, options, benefits discussed with patient

Comments: _____

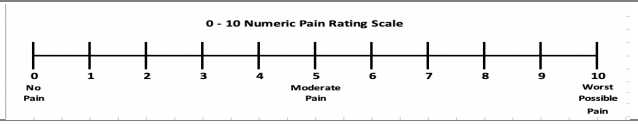
POST ANESTHESIA CARE NOTE

_____

PHYSICIAN SIGNATURE

PELOSI MEDICAL CENTER

PREOPERATIVE CARE RECORD

Immediate Preoperative Evaluation					
Procedure Date: _____/_____/_____		Driver's Name/Phone:			
Arrival Time: _____ :_____		Last time patient ate/drank: ____:____ ☐ today ☐ yesterday Describe intake:			
Pt ID verified: Yes / No		**Urine Pregnancy Test result** __ (neg.) __ (pos.) __ (n/a: age > 55 or hysterectomy)			
Vital Signs:	BP:	HR:	RR:	TEMP: ° F	Wt: lbs
Pre-Op Meds Taken:					
Pain Scale Score: _____ (0 – 10) If pain, onset ____/____/____. _____ AM/PM Location: _____					

Patient Medical/Surgical History					
Yes	**No**		**Yes**	**No**	
		Recent skin injuries			Sleep apnea
		Rash			Snoring
		MRSA (Methicillin-resistant staph aureus)			Positive HIV test
		Skin infection			Gastrointestinal problems
		Bleeding disorder			Liver problems
		Blood clots			Hepatitis
		Unusual reaction to anesthesia			Kidney problems
		Serious back or nerve injury			Diabetes
		Smoker: ☐ Past ☐ Current # packs/day ____			Hypoglycemia
		Chronic cough			Breast implants
		Lung problems			Glaucoma
		Heart problems			Drugs/Substance Use: _____
		Palpitations			_____
		Hypertension			_____
Past Surgeries/Comments: _____ _____					

Pre-op Documentation Present			Belongings/Valuables		
Yes	**No**		**Yes**	**No**	
		Completed History &Physical Exam			Hearing Aid
		Signed Informed Consent			Eyeglasses
		Lab Results (reviewed by physician)			Contact lenses
					Dental appliances
					Jewelry, cash, or other valuables
					If yes to above, Patient Valuables form (no. 063) completed

Preoperative Teaching		
Yes	**No**	
		Patient positioning during procedure
		Local anesthetic infiltration procedure
		Surgical procedure
		Pain control
		Other:

RN/Surgical Technician Signature: _____

Pelosi Medical Center

OPERATING ROOM RECORD

Date: ____/____/____	Time in OR: :	Surg. Start: :	Surg. End: :
Surgeon:	Anesthesiologist:	Surgical Technician # 1:	RN:
Surgeon Assistant:		Surgical Technician # 2:	

IV: ☐ NS ☐ RL _____ml bag started with __ gauge catheter in _____ by _____

TUMESCENT ANESTHESIA

		Bag #:	***1***	***2***	***3***	***4***	***5***	***6***	***7***	***8***	**TOTALS**
Normal Saline (0.9%)			1000 ml	1000 ml	1000 ml	1000 ml	1000 ml	1000 ml	1000 ml	1000 ml	
Sodium Bicarbonate			10 mEq	10 mEq	10 mEq	10 mEq	10 mEq	10 mEq	10 mEq	10 mEq	
Epinephrine (mg)											
Tranexamic Acid (mg)											
Lidocaine (mg)	(A)										
mls of bag infiltrated	(B)										
Initial mls in bag	(C)										
Lidocaine mg infiltrated	Ax(B/C)										

ESU: Ground Pad placed on _____ **Machine**: ☐ Ellman ☐ Covidien Cutting: ____ Coagulation: ___

2-Way 16 Fr Foley Catheter inserted pre-op: ☐ Yes ☐ No

Skin Prep Used: ☐ Betadine Scrub ☐ Betadine Solution ☐ Hibiclens Solution

Pre-op Dx:	Post-op Dx:

Procedure(s) Performed:

Counts: **Sharps** ☐ correct ☐ incorrect **Instrument** ☐ correct ☐ incorrect ☐ n/a
Sponge/Lap Pad ☐ correct ☐ incorrect ☐ n/a

Surgical Checklist Completed: ☐ Signature: _____

Intraoperative Notes:

Intake Total Volume IV Fluid Infused _____ ml	Total Tumescent Anesthetic Solution __ ml
Output Voided…..... x _____ Foley Cath ..... _____ ml	Total Volume Aspirated ___ ml - Total Infranatant Fluid _____ml Total Supranatant Fat _____ ml Total Weight Supranatant Fat (*Total Supranatant Fat ÷ 480*) = _____lb
	Fat Transfer to _____ _____ ml Fat Transfer to _____ _____ ml Fat Transfer to _____ _____ ml

Patient recovered in OR at ___:____ **PHYSICIAN SIGNATURE:** _____

PELOSI MEDICAL CENTER

ANESTHESIA RECORD

Date:	Anesthesia Start:	Surgery Start:	Surgery End:	Anesthesia End:
Surgery:		Surgeon:	Ht:	Wt:

Time	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:
Diazepam (mg PO)																						
Diphenhydramine (mg PO)																						
Oxycodone (mg PO)																						
Midazolam (mg IM / IV)																						
Fentanyl (mcg IM / IV)																						
Glycopyrrolate (mg IM / IV)																						
Metoclopramide (mg IM / IV)																						
Ondansetron (mg IM / IV)																						
Propofol (mcg/kg/min IV)																						
Oxygen (L/min)																						
ECG																						
O_2 Sat %																						
$ETCO_2$																						
Temp																						
Fluids																						

Pre-Sedation

BP:

Pulse:

RR:

SaO_2:

Monitors

- ☐ EKG
- ☐ $ETCO_2$
- ☐ SaO_2
- ☐ NIBP
- ☐ TEMP
- ☐ Other

ET# _____

LMA# _____

- ↓ Systolic BP
- ↑ Diastolic BP
- • Pulse
- O Respirations

220 – 200 – 180 – 160 – 140 – 120 – 100 – 80 – 60 – 40 – 20 –

Anesthesia Notes/Complications:

Antibiotic: _____ ____ Gm IVPB at ____:____

Patient Position: _____ ☐ Pressure points checked and padded

IV Fluid ____ ml
EBL ____ ml
Urine ____ ml

Signature: _____

PELOSI MEDICAL CENTER

POSTOPERATIVE CARE RECORD

Date:																					
Time	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:
Oxygen (L/min)																					
ECG																					
O_2 Sat %																					
$ETCO_2$																					
Temp																					
Fluids																					
220 --																					
200 --																					
180 --																					
160 --																					
140 --																					
120 --																					
100 --																					
80 --																					
60 --																					
40 --																					
20 --																					

Monitors

- ☐ EKG
- ☐ SaO_2
- ☐ NIBP
- ☐ TEMP
- ☐ Other _____

ET# _____

LMA# _____

- ↓ Systolic BP
- ↑ Diastolic BP
- • Pulse
- O Respirations

Postoperative Care and Discharge Plan

Yes	No	n/a	
			Dressings applied.
			Compression garment(s) applied: Type _____size _____
			IV access discontinued with cannula intact & no redness or edema noted.
			Foley catheter removed.
			Patient given written discharge instructions. A copy remains in the chart.
			A responsible adult is present to take the patient home.

Medications given Post-op

Time	Medication	Dose	Route
_____	_____	_____	____
_____	_____	_____	____

_____

Signature of MD/RN administering meds

1. Consciousness		3. Respiratory		5. Circulation		7. Pain		9. Oral Intake	
Conscious, fully awake	2	Deep breaths & cough freely	2	BP +- 20% of baseline	2	Pain free	2	Tolerates fluids w/o PONV	2
Arousable when spoken to	1	Dyspnea	1	BP +- 50% of baseline	1	Mild pain	1	Minimal nausea and no vomiting	1
Not responsive	0	Requiring assistive ventilation	0	BP > +- 50% of baseline	0	Unusual or excruciating pain	0	Nausea and vomiting	0
2. Activity		**4. Oxygenation**		**6. Dressing**		**8. Ambulation**		**10. Urine Output**	
Moves 4 extremities	2	Room air sats >92%	2	Dry	2	Able to ambulate appropriately	2	Voided	2
Moves 2 extremities	1	O_2 to maintain sats >90%	1	Wet but stationary	1	Dizziness or vertigo when erect	1	Has not voided	0
Cannot move extremities	0	O_2 sats <90% despite O_2	0	Wet but growing	0	Dizziness or vertigo when supine	0		

Total Aldrete Score: ____ **Score must be 18 – 20 to meet discharge criteria**

Time	Notes

Discharged from Center at ____:____ to _____ Physician Signature: _____

Pelosi Medical Center

Breast Augmentation Operative Report

Date of Procedure: _____ **Surgeon/Assistant**: _____

Anesthesia/Anesthesiologist: _____

Fluid Intake: _____ ml **EBL**: _____ ml **Drains**: ☐ None ☐ Jackson-Pratt on Right ☐ Jackson-Pratt on Left

Height/Weight/Parity: ___ft___ in / _____ lbs / _____

Pre-Operative Diagnosis: ☐ Transaxillary Subpectoral Breast Augmentation Requested

☐ Inframammary Breast Augmentation Requested

☐ Peri-Areolar Breast Augmentation Requested

☐ Other:_____

Post-Operative Diagnosis: Same

Procedure: ☐ Transaxillary Subpectoral Endoscopic Breast Augmentation with Saline Implants, Bilateral

☐ Inframammary Subpectoral Breast Augmentation with ☐ Saline ☐ Silicone Implants, Bilateral

☐ Peri-Areolar Subpectoral Breast Augmentation with ☐ Saline ☐ Silicone Implants, Bilateral

☐Primary Procedure ☐Revisionary Procedure

Round Smooth Implants: ☐Moderate ☐Moderate Plus ☐ High Profile
Right: Mentor 350-_____ Final Fill Volume: _____ **Left:** Mentor 350-_____ Final Fill Volume: _____

Clinical Findings:
This is a ___-year-old female with a pre-operative diagnosis described above who after a discussion of the risks, benefits and expected outcomes of all treatment alternatives, consented to the procedure described above and signed written informed consent.

Description of Procedure:
The patient was marked for ☐ transaxillary ☐ inframammary ☐ peri-areolar ☐subpectoral ☐ subglandular breast augmentation and photographs were taken. She was brought to the operating room, intravenous access was established and prophylactic antibiotics were administered. She was positioned comfortably for surgery.

She was then placed under an adequate level of anesthesia, then prepped and draped in the usual sterile fashion for breast augmentation. Anti-embolic pneumatic compression stockings were placed on the lower extremities.

The procedure was initiated on the ☐ right ☐ left side.

☐ Trans-axillary breast augmentation was initiated. After injecting the axillary skin and subcutaneous tissue with 50mL of dilute lidocaine solution, a 4-cm skin incision was made in a transverse direction along a skin crease.

☐ Since this was a primary case, superficial subcutaneous dissection was carried out to expose the lateral border of the pectoralis major muscle. The lateral fascia over the pectoralis major muscle was divided and the subpectoral space was entered laterally under the upper portion of the pectoralis major muscle. No undue bleeding was encountered during this dissection. Gentle, blunt finger dissection beneath the pectoralis major muscle was made extending as far laterally and inferiorly as possible to create a space for the endoscope. The space was further dissected with a blunt breast dissector with a gentle sweeping motion.

The endoscope was attached to the endoscopic retractor and advanced through the incision into the subpectoral space under direct video surveillance without complications. The undersurface of the pectoralis major, the juncture of the muscles origins, and the chest wall and ribs were clearly identified. The unipolar spatula was advanced into the subpectoral space and employed to divide the pectoralis major muscle from the level of the areola extending inferiorly and laterally to the lateral extent of the muscle staying approximately 1 cm above the chest wall, avoiding damage to the undersurface of the breast skin, and maintaining absolute hemostasis.

The endoscope was removed and the Agris-Dingman dissector was inserted into the subpectoral space. With a gentle, blunt sweeping motion, the lower pocket was advanced to the level of the new inframammary fold. The lateral aspect of the pocket was dissected bluntly in a similar fashion with care taken to avoid damage to the antero-lateral sensory nerves. Hemostasis was confirmed endoscopically following this maneuver.

A breast sizer was inserted through the incision into the subpectoral space, inflated with air to the volume of the proposed implant and the adequacy of the pocket was confirmed. The sizer was left in place and the operation was repeated uneventfully on the contralateral side.

Pelosi Medical Center

Breast Augmentation Operative Report

Both implant pockets were then assessed for symmetry. The breast sizer was deflated and removed, the implant pocket was re-assessed endoscopically, hemostasis was confirmed, and the pocket was irrigated thoroughly with saline solution containing an antibiotic.

☐ Since this was a revisionary ☐ axillary ☐ inframammary ☐ peri-areolar case, superficial subcutaneous dissection was carried out to expose the existing breast implant capsule. The capsule was opened with a combination of sharp and electrosurgical dissection and the breast implant was exposed. The implant was then drained and removed.

The breast implant was prepared according to the manufacturer's directions, inserted through the incision in proper alignment with care taken to avoid touching the skin, then inflated with saline to the minimum implant volume. The fill valve was left attached.

☐ The procedure was limited to the ☐ right side ☐ left side.

☐ The procedure was repeated contralaterally.

The patient was then placed in a seated position to confirm symmetry, small volume additions were made to reach the desired final implant volume(s), the fill valves were removed from the implants, and the skin incisions were closed in layers with 4-0 delayed-absorbable monofilament sutures.

Dressings were placed over the skin incisions. She tolerated the procedure well and was brought to the recovery area in stable condition.

_____ _____

Surgeon Signature Date