

IDEAL IMPLANT® SALINE-FILLED BREAST IMPLANTS

April 2009

CAUTION: Investigational device. Limited by Federal law to investigational use.
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INTRODUCTION – DIRECTIONS TO THE PHYSICIAN

The information supplied in this physician labeling document is intended to provide an overview of essential information about IDEAL IMPLANT® Saline-Filled Breast Implants, including a device description, the indications for use, contraindications, warnings, precautions, important factors to discuss with a patient, adverse events, other reported conditions, returned devices, product evaluation, and returned goods authorization.

Patient Counseling Information

You should review this document and patient labeling prior to counseling the patient about IDEAL IMPLANT Saline-Filled Breast Implants and breast implant surgery. Please familiarize yourself with the content of this document and resolve any questions or concerns prior to proceeding with use of the device. As with any surgical procedure, breast implantation is NOT without risks. Breast implantation is an elective procedure, and the patient must be well counseled and understand the risk/benefit relationship.

Before making the decision to proceed with surgery, the surgeon or a designated patient counselor should instruct the patient to read ***Important Information for Women about IDEAL IMPLANT® Saline-Filled Breast Implants*** (patient labeling) and discuss with the patient the warnings, contraindications, precautions, important factors to consider, complications, and all other aspects of the patient labeling. The physician should advise the patient of the potential complications and that medical management of serious complications may include additional surgery and explanation.

Informed Decision

Each patient should receive Ideal Implant Incorporated's ***Important Information for Women about IDEAL IMPLANT® Saline-Filled Breast Implants*** during her initial visit/consultation, to allow her sufficient time to read and adequately understand the important information on the risks, follow-up recommendations, and benefits associated with saline-filled breast implant surgery.

DEVICE DESCRIPTION

The IDEAL IMPLANT is a round, smooth-surface, saline-filled breast implant that is supplied sterile in a double wrapped packaging system. It was developed so women can have the option of a breast implant that is unlike the current saline-filled implants or the current silicone gel-filled implants.

The IDEAL IMPLANT is made from the same materials as standard saline-filled breast implants. However, while standard saline-filled implants have a single shell made from successive cross-linked layers of silicone elastomer, the IDEAL IMPLANT has three to

five shells of slightly increasing size. There is an inner shell with a valve in the posterior patch for filling an inner lumen. Surrounding this are one to three unattached, perforated shells. Finally, surrounding these perforated shells, is an outer shell with an anterior valve for filling an outer lumen. The inner and outer lumens are filled with saline after the implant has been placed in a submuscular or subglandular pocket.

The internal structure of the IDEAL IMPLANT was designed to restrict movement of the saline filler. In addition, this internal structure was designed to support the upper pole and edge. The fill volumes were established so that when placed on a convex surface, the edge of the implant is low.

Component Shells

Catalogue Number	Size*	Inner	Unattached, Perforated	Outer	Total Shells
44 – 184	184cc	1	1	1	3
44 – 210	210	1	1	1	3
44 – 238	238	1	1	1	3
44 – 265	265	1	1	1	3
44 – 295	295	1	2	1	4
44 – 325	325	1	2	1	4
44 – 360	360	1	2	1	4
44 – 390	390	1	2	1	4
44 – 425	425	1	2	1	4
44 – 460	460	1	2	1	4
44 – 495	495	1	2	1	4
44 – 530	530	1	3	1	5
44 – 565	565	1	3	1	5
44 – 600	600	1	3	1	5

*Total implant volume at minimum fill in the outer lumen

Approximate Dimensions and Volumes

Catalogue Number	Size cc	Diameter* mm	Projection* mm	Inner Lumen	Outer Lumen			Total Implant Volume		
					Low	Mid	High	Low	Mid	High
44 – 184	184	99.5	31.2	122cc	33	47	61cc	184	198	212cc
44 – 210	210	104.0	32.2	142	35	51	67	210	226	242
44 – 238	238	108.5	33.2	165	38	56	74	238	256	274
44 – 265	265	112.5	34.2	188	40	60	79	265	285	304
44 – 295	295	116.0	35.2	188	55	76	97	295	316	337
44 – 325	325	119.5	36.2	212	58	82	105	325	349	372
44 – 360	360	123.0	37.2	236	64	89	114	360	385	410
44 – 390	390	126.5	38.2	261	66	93	121	390	417	445
44 – 425	425	129.5	39.2	288	69	96	124	425	452	480
44 – 460	460	132.5	40.2	317	71	101	131	460	490	520
44 – 495	495	135.5	41.2	344	75	107	140	495	527	560
44 – 530	530	138.5	42.2	344	92	125	158	530	563	596
44 – 565	565	141.5	43.2	373	90	125	160	565	600	635
44 – 600	600	144.5	44.2	403	87	124	161	600	637	674

*measured on a convex surface at minimum fill in the outer lumen

TARGET INTENDED USE

The IDEAL IMPLANT is being investigated for safety and effectiveness for primary breast augmentation or replacement of existing saline-filled or silicone gel-filled augmentation implants in women 18 years of age or older.

INCLUSION CRITERIA

- Is a genetic female, 18 years of age or older.
- Is a US citizen and primarily resides within 100 miles of investigator.
- Has an email address.
- Is undergoing one of the following:
 - bilateral primary breast augmentation, and has dissatisfaction with breast size and wishes breast enlargement
 - bilateral replacement augmentation and has had previous augmentation with silicone gel-filled or saline-filled implants.
- Agrees to sign the Informed Consent which includes HIPAA authorization.
- Agrees to sign a Medical Records Release form.
- Agrees to comply with post-operative instructions.
- Agrees to follow the procedures for explant analysis including to authorize return of the implant to Ideal Implant Incorporated if the implant is explanted.
- Agrees to comply with follow-up requirements including email contacts, visits, and questionnaires.

EXCLUSION CRITERIA

- Plans to become pregnant within six months of the procedure.
- Has nursed a child within three months of study enrollment.
- Has a condition that could compromise or complicate wound healing.
- Has a diagnosis of active cancer of any type.
- Has ever been diagnosed with breast cancer.
- Has pre-malignant breast disease.
- Has an infection or abscess anywhere in the body.
- Has tissue characteristics incompatible with an implant, such as inadequate tissue cover or compromised vascularity.
- Has any condition, or is under treatment for any condition which, in the opinion of the investigator, may constitute an unwarranted surgical risk.
- Has anatomic or physiologic abnormality that could lead to significant post-operative adverse events.
- Has unrealistic/unreasonable expectations of the procedure results.

WARNINGS

1. ***Avoiding Implant Damage During Surgery and Medical Treatment or Procedures***

- iatrogenic events inadvertently induced by a physician or surgeon, or by medical treatment or procedures, may contribute to premature implant failure.
- Do not allow sharp instruments, such as scalpels or needles, to contact the device during the implantation or other surgical procedures. Women should be instructed to inform other treating physicians to observe this warning.

- An incision should be of appropriate length to accommodate the empty, rolled implant.
- Avoid creating wrinkles or folds in the device during the implantation or other procedures. A typical practice is to run your finger around the implant after it is filled, but before closing the incision, to ensure the implant is lying flat and has no folds or wrinkles. Submuscular placement of the device makes the inspection for wrinkles or folds more difficult.
- Do not treat capsule 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 evacuation, biopsy, and lumpectomy to avoid damage to the implant shell. Re-positioning of the implant during subsequent procedures should be carefully evaluated by the medical team and care taken to avoid contamination of the implant. Use of excessive force during any subsequent procedure can contribute to localized weakening of the implant shell, potentially leading to decreased performance.
- Do not contact the implant with cautery devices.
- Do not place drugs or substances in the implant other than sterile 0.9% Saline for Injection.
- Do not immerse the implant in Betadine solution or place Betadine solution in the implant. The pocket may be irrigated with a solution of equal parts Betadine and normal saline.
- Do not alter the implant or attempt to repair or insert a damaged implant.
- Do not re-use or re-sterilize an implant that has been previously implanted. This implant is intended for single use only.
- Do not place more than one implant in a surgical pocket.

2. **Microwave Diathermy**

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

PRECAUTIONS

1. **Specific Populations**

Safety and effectiveness has not been established. CAUTION: This is an investigational device. Limited by Federal law to investigational use.

2. **Surgical Precautions**

- **Surgical technique** – The implantation of saline-filled breast implants involves a variety of surgical techniques. Therefore, the surgeon is advised to use the method that her/his own practice and discretion dictate to be best for the patient, consistent with this Instructions for Use. A backup implant should be available in the operating room. The surgical technique for inserting the IDEAL IMPLANT is the same as for a standard saline-filled implant, except for filling two separate lumens.
- **Device integrity** - The implant should be tested for patency and shell integrity immediately prior to use. This can be accomplished by gently compressing the implant while carefully examining for leakage of the air inside.
- **Filling procedure** - Diaphragm valves are normally in the closed position. When the plug on the end of a fill tube is inserted into a valve, the diaphragm is held open, allowing the flow of air or saline. When the fill tube plug is removed, the diaphragm

closes, sealing the valve. Overstressing the valve can cause damage such as punctures or tears and result in implant deflation. Use only the fill tube plug designed for and provided with this implant.

- Since this implant has an inner lumen and an outer lumen that require different fill volumes, the two respective fill tubes must not be confused once the implant is in the surgical pocket. For this reason, one fill tube is unmarked and is for the valve on the front of the implant while the other fill tube is marked: “**BACK---BIG---BEGIN**”
 - **BACK** - for the valve on the **BACK** of the implant
 - **BIG** - for the inner lumen that has a **BIG** fill volume compared to the outer lumen
 - **BEGIN** - it is technically easier to **BEGIN** by filling the inner lumen and remove this fill tube from the back of the implant before filling the outer lumen from the front.
- Remove and discard the protective strips between the valve straps and the valves. Wet the fill tube plugs in sterile isotonic saline for lubrication, slide the valve straps to one side and insert the plugs into the valve openings, using thumb and forefinger to stabilize the valves. While rotating slightly, gently push the fill tube plugs into the valve openings as far as the flanges permit. Be certain that the fill tube marked “**BACK---BIG---BEGIN**” is inserted into the valve on the **BACK** of the implant and the unmarked fill tube is inserted into the valve on the front of the implant.
- When the valves are open, air will freely escape from both lumens as the implant is compressed. Attach a check valve to each luer lock and use an empty, sterile syringe to completely deflate each lumen. This minimizes the size of the implant for easier passage through the incision. Remove the syringe, roll the implant, moisten it with saline for lubrication and insert it into the prepared pocket.
- Use only sterile, pyrogen-free 0.9% Sodium Chloride U.S.P. Solution for Injection drawn from its original container, since infection may result from contaminated saline. For this reason, a closed injection system is recommended consisting of intravenous bag, intravenous tubing, 3-way stopcock and syringe. This closed system is connected to the sterile fill tubes supplied with the implant.
- Follow the Instructions for Use and implant label for the recommended fill volumes of the **BIG** inner lumen and the small outer lumen. For each implant, the recommended fill volumes were calculated so they are proportionate to the implant size and the capacity of the inner and outer shells. This gives the implant optimal performance.
- Do not overfill or underfill the inner lumen or the outer lumen as this may cause wrinkles, scallops and/or deflation from crease/fold failure. When filling, allow for the 3cc of saline inside each fill tube.
- Consider that the convexity of the chest wall pushes in the back of a breast implant, an effect like adding fill volume. If the convexity is more than average, the effect is more and outer lumen fill may be chosen at the lower limit of the fill range; if the convexity is less than average, the effect is less and outer lumen fill may be chosen at the upper limit of the fill range.
- **BEGIN** with the fill tube marked “**BACK---BIG---BEGIN**” that is inserted into the valve on the **BACK** of the implant for the **BIG** volume inner lumen. When the inner lumen is filled, remove its fill tube before using the unmarked fill tube that is inserted into the valve on the front of the implant for the small volume outer lumen. When the outer lumen is filled, remove its fill tube.

- Any remaining air in the implant will eventually diffuse out and be absorbed by the tissue. It is not necessary to remove the small amount of entrapped air.
- Use care when removing the fill tube plugs from the valves to prevent damage to the valve assemblies. Support the area around each valve with fingertips and pull the fill tube plug straight out, not at an angle to the valve.
- Position the valve strap over each valve and insert the protective strap plug into the valve opening.
- **Implant Selection** - Some of the important surgical and implant sizing variables that have been identified include the following:
 - The implant should be consistent in size with the patient's chest wall dimensions, including base width measurements, bearing in mind the laxity of the tissue and the projection of the implant.
 - A thorough discussion should be conducted with the patient, employing appropriate visual aids such as imaging, sizing implants, or other options to clarify their objectives and reduce the incidence of subsequent operation for size change.
 - The following may cause implants to be more palpable: larger implants, subglandular placement, and an insufficient amount of skin/tissue available to cover the implant.
 - Available tissue must provide adequate coverage of the implant.
 - Larger sized implants (>350cc) may increase the risk of developing complications such as implant extrusion, hematoma, infection, palpable implant folds and wrinkling requiring surgical intervention to correct these complications.
- **Incision Site Selection**
 - The periareolar incision is typically more concealed, but is associated with a higher likelihood of difficulties in successfully breast feeding as compared to other incision sites. A periareolar incision may result in changes in nipple sensation.
 - The inframammary incision is generally less concealed than the periareolar, but it is associated with less breast feeding difficulty than the periareolar incision site.
 - The axillary incision is less concealed than the periareolar site.
 - The umbilical incision avoids a scar on the breast, but the approach may be more difficult.
- **Implant Placement Selection** - A well-defined, dry pocket of adequate size and symmetry must be created to allow the implant to be placed flat on a smooth surface.
 - Submuscular placement may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to perform some subsequent operative procedures than subglandular placement. The possible benefits of this placement are that it may result in less palpable implants, less likelihood of capsule contracture, and easier imaging of the breast for mammography. Also, submuscular placement may be preferable if the patient has thin or weakened breast tissue.
 - Subglandular placement may make surgery and recovery shorter, may be less painful, and may be easier to access for a subsequent operation than the submuscular placement. However, this placement may result in more palpable implants, greater likelihood of capsule contracture, and increased difficulty in imaging the breast with mammography.
- **Maintaining Hemostasis/Avoiding Fluid Accumulation** - Careful hemostasis is important to prevent post-operative hematoma formation. Should excessive bleeding persist, implantation of the device should be delayed until bleeding is controlled. Post-operative evacuation of hematoma or seroma must be conducted with care to

avoid breast implant contamination, or damage from sharp instruments, retraction, or needles.

- **Recording Procedure** - Each breast implant is supplied with one Patient Implant Card and six Implant Record Labels showing the size, catalog number and serial number for that implant. The Patient Implant Card and Implant Record Labels are located inside the shelf box. To complete the Patient Implant Card, adhere one Implant Record Label for each implant on the back of the Patient Implant Card. Another label should be affixed to the patient's chart. The implanted position (right or left side) should be indicated on the label as well as the volume of saline placed in the inner lumen and in the outer lumen. If an Implant Record Label is unavailable, size, catalog number, serial number and description of the implant may be copied by hand from the implant label. The patient should be provided with the Patient Implant Card for personal reference.
- **Post-operative Care** - You should advise your patient that she will likely feel tired and sore for several days following the operation, and that her breasts may remain swollen and sensitive to physical contact for a month or longer. You should also advise her that she may experience a feeling of tightness in the breast area as her skin adjusts to her new breast size. For at least a couple of weeks, the patient should avoid any strenuous activities that could raise her pulse and blood pressure. She should be able to return to work within a few days. Breast massage exercises may also be recommended as appropriate.

INFORMATION FACTORS TO BE DISCUSSED WITH WOMEN AS PART OF PHYSICIAN CONSULTATION

Breast implantation is an elective procedure and the patient must be thoroughly counseled on the risks, as well as the benefits, of these products and procedures. You should advise your patient that she must read the Patient Information Booklet. You must read the Patient Information Booklet in its entirety. The booklet is intended as the primary means to relate uniform risk and benefit information to assist your patient in making an informed decision about primary breast augmentation and replacement of existing augmentation implants, but is not intended to replace consultation with you.

Below are some of the important factors your patients need to be aware of when using IDEAL IMPLANT saline-filled breast implants. Section 1.4 of the Patient Information Booklet provides a more detailed listing of important factors for patients.

- **Shell failure** - Breast implants may not last a lifetime. Failure of the inner shell and/or the outer shell can occur due to wear from stresses or manipulations during daily routines such as vigorous exercise, contact athletics, manual massage or intimate physical contact.
 - Failure of the inner shell and outer shell deflates both the inner lumen and outer lumen. The saline is absorbed by the body. Implant fullness decreases significantly, which is obvious to patient and surgeon. If this occurs, the implant should be removed, with or without replacement. If the deflated implant is replaced promptly, before the capsule contracts, the procedure may be done using local anesthesia in the area of the original incision, rather than general anesthesia or intravenous sedation.
 - Failure of only the outer shell deflates just the outer lumen. The saline is absorbed by the body. Implant fullness decreases slightly, which may or may not be obvious. However, the implant feels different to patient and surgeon. It feels

more like a standard saline implant because the saline moves in one lumen without an internal structure to restrict its movement. Also, the implant edges feel thicker and more palpable because the outer and perforated shells collapse together onto the inner shell. The sonographic image is characteristic and can be used to confirm the diagnosis. If this occurs and there is a cosmetic concern, removal, with or without replacement, may be recommended. Otherwise, no treatment is needed until the inner shell fails, the implant deflates and removal, with or without replacement, is recommended.

- Failure of only the inner shell does not cause a decrease in implant fullness. However, the implant feels different to patient and surgeon. It feels more like a standard saline implant because the saline moves in one lumen without an internal structure to restrict its movement. Also, the implant edges feel thin in some areas and thick and more palpable in others because the inner and perforated shells collapse together in the interior. The sonographic image is characteristic and can be used to confirm the diagnosis. If this occurs and there is a cosmetic concern, removal, with or without replacement, may be recommended. Otherwise, no treatment is needed until the outer shell fails, the implant deflates and removal, with or without replacement, is recommended.
- **Explanation** - Implants are not considered lifetime devices, and women likely will undergo implant removal(s), with or without replacement, over the course of their life. When implants are explanted without replacement, changes to the patient's breasts may be irreversible. Complication rates are higher following replacement surgery.
- **Subsequent operation** – Additional surgeries to the women's breasts and/or implants will likely be required, either because of deflation, other complications, or unacceptable cosmetic outcomes. Women should be advised that their risk of future complications increases with subsequent operations as compared to the primary augmentation. There is a risk that implant shell integrity could be compromised inadvertently during subsequent operations, potentially leading to product failure.
- **Infection** – Signs of acute infection reported in association with breast implants include erythema, tenderness, fluid accumulation, pain, and fever. In rare instances, as with other invasive surgeries, Toxic Shock Syndrome (TSS) has been noted in women after breast implant surgery, and it is a life threatening condition. Symptoms of TSS occur suddenly: a high fever (102° F, 38.8° C or higher), vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches and drops in blood pressure which may cause fainting. Women should contact a physician immediately for diagnosis and treatment of any of these symptoms.
- **Breast Examination Techniques** – Women should perform breast self-examinations monthly and be shown how to distinguish the implant from their breast tissue. The patient should not manipulate or squeeze the implant excessively.
- **Mammography** – Women should be instructed to undergo routine mammography exams as per their primary care physician's recommendations. The importance of having these exams should be emphasized. Women with breast implants of any type should be instructed to inform their mammographers about the presence, type, and placement of their implants. Also, they should request a diagnostic mammography, rather than a screening mammography, because more pictures are taken with diagnostic mammography. Breast implants of any type may complicate the interpretation of mammographic images by obscuring underlying breast tissue and/or by compressing overlying tissue. Accredited mammography centers, technicians with experience in imaging women with breast implants, and use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast. The current recommendations for pre-operative/screening

mammograms are no different for women with breast implants of any type than for those women without implants. Presurgical mammography with a mammogram following the procedure may be performed to establish a baseline for routine future mammography in augmentation patients.

- **Lactation** – Breast implant surgery may interfere with the ability to successfully breast feed, either by reducing or eliminating milk production.
- **Avoid Damage During Treatment** – Women should inform other treating physicians of the presence of implants to minimize the risk of damage to the implants.
- **Smoking** – Smoking may interfere with the healing process.
- **Radiation to the Breast** – Radiation therapy may increase the likelihood of capsule contracture, necrosis, and implant extrusion.
- **Insurance coverage** – Women should be advised that health insurance premiums may increase, insurance coverage may be dropped, and/or future coverage may be denied based on the presence of breast implants. Treatment of complications may not be covered as well. Women should check with their insurance company regarding coverage issues before undergoing surgery.
- **Mental Health and Elective Surgery** – It is important that all women seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Request that your patient openly discuss with you, prior to surgery, any history that she may have of depression or other mental health disorders.
- **Long-Term Effects** – Ideal Implant Incorporated will continue its Core Study through 10 years to provide information on long-term safety and efficacy of this product.

ADVERSE EVENTS

Undergoing any type of surgical procedure involves risks (some serious) such as the effects of anesthesia, infection, swelling, redness, bleeding, pain, and even death, which need to be balanced against the benefits of the breast augmentation surgery. There are potential complications specific to breast implant surgery and breast implants, as described below.

Major Surgery and Anesthesia Related Risks

All surgical procedures have a small risk of complications inherent to the surgery itself and to anesthesia. These include:

- Anesthesia complications including allergic reactions and anaphylaxis
- Cardiac complications such as arrhythmia, myocardial infarction
- Pulmonary complications such as aspiration, atelectasis, pneumonia
- Pulmonary embolus
- Deep venous thrombosis
- Neurologic complications such as stroke, pressure neuropathy
- Death

Breast Implant Related Risks

- **Capsule contracture**
- **Capsule calcification and calcium deposits**
- **Wrinkling/scalloping**
- **Spontaneous failure of the inner shell**
- **Spontaneous failure of the outer shell**
- **Spontaneous deflation**
- **Seroma**

- **Breast tissue atrophy/chest wall deformity**
- **Interference with mammography**
- **Dissatisfaction with cosmetic result**

Subsequent operations related to presence of implants - Women should understand there is a high chance they will need to have a subsequent operation at some time related to an implant problem such as capsule contracture, spontaneous deflation, wrinkling or seroma. Many women decide to have the implants replaced, but some women do not. Those who do not may have cosmetically unacceptable dimpling and/or puckering of the breast following implant removal. Implant replacement increases the risk of complications such as capsule contracture and the need for subsequent operations.

Breast Procedure Related Risks

- **Hematoma/bleeding**
- **Wound infection (not peri-prosthetic)**
- **Wound healing delay, tissue necrosis, dehiscence (no exposure)**
- **Peri-prosthetic infection (no exposure)**
- **Septicemia**
- **Implant exposure/extrusion**
- **Skin scar unsatisfactory**
- **Mastopexy unsatisfactory**
- **Implant position unsatisfactory (malposition)**
- **Persistent breast pain**
- **Nipple/breast sensitivity change**
- **Lactation problem**
- **Lymphadenopathy**

Subsequent operation related to surgical procedure for implant placement - Women should understand there is a chance they will need to have subsequent operations at some time related to problems from the surgical procedure for implant placement. Examples include control of bleeding or treatment of an infection.

Other Reported Conditions and Risks

- **Dissatisfaction with implant size selected – bilateral**
- **Dissatisfaction with implant size selected - unilateral (asymmetry)**
- **Trauma to implant – surgical procedure**
- **Trauma to implant – external**
- **Breast ptosis - after implant placement procedure due to pregnancy, weight change and/or breast size change**
- **Breast lesion – benign**
- **Breast lesion – malignant**
- **Connective tissue disease**
- **Reproduction problem**
- **Suicide**

Subsequent operation unrelated to presence of implant or surgical procedure for implant placement - Women should understand there is a chance they will need to have subsequent operations at some time for problems unrelated to the implant or the surgical procedure for implant placement. Examples include change in implant size or replacement due to trauma to the implant.

PATIENT IMPLANT CARD

Each breast implant is supplied with a Patient Implant Card and six Implant Record Labels inside the shelf box. To complete the Patient Implant Card, place one Implant Record Label for each implant on the back of the card. If a label is unavailable, the serial number, size, catalog number and description of the implant may be copied by hand from the implant label. The patient should be provided with the Patient Implant Card for personal reference.

EXPLANT RETURN

Return explanted implants to Ideal Implant Incorporated, Product Evaluation Department, 2445 Gateway Drive, Suite 130, Irving, Texas, 75063 for examination and analysis. Call 214-492-2500 for instructions and shipping information.

PRODUCT EVALUATION

Ideal Implant Incorporated requires that any complications or explanation resulting from use of this implant be brought to the immediate attention of Ideal Implant Incorporated, Product Evaluation Department, 2445 Gateway Drive, Suite 130, Irving, Texas, 75063.

REPORTING PROBLEMS WITH AN IMPLANT

FDA requires that serious injuries (defined as those that need medical or surgical intervention to prevent permanent damage) be reported by hospitals if they are aware of the serious injuries. If you have a patient who has experienced one or more serious problems related to her breast implants, you must report the serious problem(s) to Ideal Implant Incorporated and your IRB. Examples of serious problems include, death, disability, hospitalization, harm to offspring, and medical or surgical intervention to prevent lasting damage.

RETURNED GOODS POLICY

Merchandise returned must have all manufacturers' seals intact and must be returned within 10 days from date of invoice to be eligible for credit or replacement. Please contact Ideal Implant Incorporated for details.

LIMITED WARRANTY

The Ideal Implant Incorporated Breast Implant Limited Warranty provides lifetime replacement and limited financial assistance in the event of inner shell failure and/or outer shell failure, subject to certain conditions as described in the Breast Implant Limited Warranty literature. For more information, contact Ideal Implant Incorporated at 214-492-2500.

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