Should I replace them with Saline? What should I do? And nobody can give them an answer.

WOMAN: And you cannot speak to any of those issues because that is medical advice and that is the last thing we want to do is to get into litigation with giving any medical advice whatsoever.

PAULETTE: We are going to go over that to. We are not medical doctors and we, under no circumstance, give medical advice ever, ever, ever. There is a real good come back to that, if she says what should I do...The comeback is that you have to understand that I am voice on the other end of the phone, I can't see you, I don't know you, I don't know your medical history. I don't know anything about you. You have to go to your physician, he knows you, he knows your medical history, he knows all about you. I don't. As a matter of fact I had one that said "you're right". They are in such a helter skelter over what should I do and their concerns and everything they are not thinking logically. Sometimes you have to point it out to them, I don't know you, I can't see you, I don't know how tall you are, what you weight, I don't know anything about you.

WOMAN: They are just desperate for answers. [mixed conversation] ... of family doctors working with them, just somebody they went to and so they really don't have any security even if they are physicians.....

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TAPE 4 SIDE A

PAULETTE: ....we are going over surgical procedures and then watch a film, so I'll talk to you a little bit first so you will know what you are seeing in the film.

Breast augmentation can take place for many reasons. One of the reasons is to correct developmental deformities, spectrical hypophasa when both breasts are to small. Asymmetrical hypophasa ...

WOMAN: Could we get a copy of that because I don't know how to spell those?

PAULETTE: Traumatic deformities [indiscernible], after severe burns, after radiation treatment for cancer. Malignancy surgery for removal of malignant tissues or post mastectomy [verbal to low].... is the ..... They use implants to correct .... it's like gravity ... aging ... and occupational needs deals with models. The primary consideration for breast augmentation is enlargement of breasts to a size contoured form that is symmetrical and acceptable to the patient. Most patients are not concerned with incisions when the aredema fades which particularly if the breasts are soft and attractive. I do have to say that now a lot of women are concerned with where the incision and the scar will lead. Selection of the incision location must be individualized. Three incisions often used for breast augmentation are in the mammary, currirealur and auxiliary, and we will talk about those.

The auxiliary incision which is under the arm, the doctor comes under the arm, comes in with an instrument and sweeps the area to create a pocket to hold the implant. They must put the implant in under the arm, of course, there are pros and cons to each incision site. One of the cons to do this is that the doctor is [low verbal] and one of the things you must ask for implant is a dry pocket, it has to be catherized, it has to be dry to be put in, [low verbal]. The good thing about this the pro about this, with the incisions under the arm is that you don't see it.

Currirealur which is around the nipple, is minimal scarring. I have seen these, very small, very [low verbal] except I do want to mention here to that you have all heard about Jennie Jones, she has had her implants replaced 5 times and she talks about, she has no sensation whatsoever, her nipple is large and distended and misshapen. All 5 times they went in .... I'm not surprised she doesn't have sensation. Five surgeries in the same place. I don't know why anybody wouldn't think to go another way. [low verbal]. There is fair visualization when you go in this way [low verbal].

If ... it leaves a visible scar although you don't usually see it. People do complain that this scar is visible, they have really good visualization, they can see the pocket, they can sweep the pocket and this is a way that a lot of them are done, although this one ... painful .... and scars.

Once the implant is in. There are two places you can put that implant, you can put it

subglandular which is beneath the breast tissue and it is the easiest one to do. What they do is take the mammary gland, create the pocket underneath it, slip it on top of the pectoral muscle and right under the gland ... sits there, creates the pocket there, scar tissue forms around it nicely there.

The next one is [undiscernible] take this muscle and split it in half and insert the implant..

WOMAN: What are the advantages of splitting the muscle?

PAULETTE: What some doctors believe is that there is less capsilliary contracture. And that will make more sense to you as we talk about the capsilliary contracture. It is the main pectoral major muscle [coughing] what you need to do, some surgeons believe that this site reduces capsilliary contracture. In placing an implant beneath the muscle, the surgeon must use a larger implant to achieve the larger projection due to the distance from the breast about half of all implants are inserted [undiscernible] to reduce capsilliary contracture. Another advantage, at least as what they are saying is an advantage, of the submuscular over the in the mammary, that if it is beneath the muscle like this one is, then you can pull the breast tissue also, during a mammogram they do what is called the pinch step [low verbal] and push the implant back to the chest wall and pull the breast tissue out. I have seen it done and the woman that I saw it done [low verbal]. I don't know if any of you have had a mammogram -- I have.

AUDIENCE: Yes.... It's not comfortable.

PAULETTE: I didn't. I had no problems whatsoever.

WOMAN: The first one I had wasn't comfortable but I had one just a couple of weeks ago it was fine.

[audience all talking at once]

PAULETTE: It does depend on the technician and women with implants, this is the question we gotten from them. The thing that they need to remember is that they need to tell them first off is that they had an implant, they need to know this because the compression that they use is different if you have an implant than if you don't have an implant. They don't use as much compression. The second thing is that they are going to do two techniques, they do as you know for those of you who have had mammograms they do four views of the breast. They do when you have an implant they do four views with the implant in place and four views pushing it back against the chest wall. So they are doing eight actually if you have an implant. That's another reason because they can hold that breast tissue out more if it's [low verbal].

WOMAN: Oh yesterday on one of the films we saw, are women, showed how you couldn't see anything.

PAULETTE: That was the one that was supposed to see through gold.

WOMAN: Was that one of the reasons ....

PAULETTE: I don't believe they said whose implant that was. But I am glad that you remembered that because they didn't not use the pinch technique in that obviously. They were using just the first views and this happens a lot of times in the media we just hear one portion of it. We don't hear the whole thing. Literally, I have seen the X-rays after what they call the pinch technique and the regular one, there is quite a difference. They can really pull a lot of tissue out.

During the last Advisory Panel Hearings a lot of groups were there and they really stated their case very well. Even when I attended that meeting last year, they felt that they really were getting a bad [low verbal]. They could see much more tissue than what it was being accused of. Another thing that I might tell you, if you are having an uncomfortable mammogram, and you certainly can tell when you are, because that is why that I went, I said hey I need to tell these ladies something, I need some answers. If you avoid caffeine a week before you have it..

WOMAN: That's where they lost me.

PAULETTE: If you do not go the first five days of your cycle and the last thing and the most important thing, is that this is a once year event, very very few medical procedures are non-invasive and even if hemoglobin, it is a pick in the finger and painful. But it is important when breast cancer is 1 in 9 these women continue to have their mammograms. And, I have heard women on the phone say, pinch technique, this is as painful as child birth and I will never do it again.

WOMAN: But you know you have different pain levels.

PAULETTE: This is true.

WOMAN: Some women have extremely sensitive breasts even to the touch.

PAULETTE: Exactly. The only thing that we can do is try help them through, sympathize, give them the few things that we have, you know avoid caffeine, those are really the only things that I have to give them.

WOMAN: That's the only "medical advice" you would give.

PAULETTE: I don't really believe that is medical advice. It is just common knowledge that caffeine will make your breast tender, your breasts do become tender during the first 5 days of your cycle. Those are times to avoid. And, for your own knowledge and certainly you can share with whoever is on the telephone if you care to. In the breast [low verbal], I am not really good at this. When we do a mammogram it is divided into four areas like this. 45 to 47% of all cancers are found in this quadrant of the breast and they can see all of the bad tissue during a mammogram whether you have an implant or you don't have an implant.

AUDIENCE: You said 40 to 45%.

PAULETTE: 45 to 47%.

WOMAN: Wow.

PAULETTE: In the [low verbal] quadrant of the breast. The percentage of the tissue they can't see is about 7% and it's what lies behind the implant, what is on the chest wall, that is what they can't see.

WOMAN: That's 7%.

PAULETTE: I don't want to get off too much on mammography, but you will also hear the statement from women that [coughing], understand that if their nipple is off, if the skin is off they can still develop cancer. You do not tell them to have a mammogram, that is not your business to do. But certainly they need to check with their doctor how they need to be. I will tell you that the reconstruction patients are some of the most educated patients that you will ever talk to, they have been through a lot and they know what they are talking about. I wanted to show you, I do not have a film on reconstruction, a lot of reconstruction is done today. But this is a lot of what the surgery looks like. Another thing that we'll talk about later to is that during mastectomy usually, they will also take the lymph nodes at the same time and then when you talk about where did the gel go, you will talk about [low verbal] lymph nodes. I understand that doctors are really becoming better at not mutilating women during mastectomy surgery because they have had some horrible scars.

WOMAN: To you being a woman kind of says it all.

PAULETTE: .....scars of women. I'm going to talk about implant positioning, submuscular or subpectoral or, I'm sorry, subglandular. And you will hear it also submammary is the mammary gland, you will also hear muscular phasural, all kinds of terms. Implant position is a key factor to obtaining an excellent result for augmentation mammoplasty. When operations first breast enlargement were first developed, implants were placed over the chest wall [undiscernible]. This seemed to be the natural position to enlarge the breastline. With this retro-mammary position, there was and continues to be capsilliary contractures around the implant. This condition has developed despite the use of different implants, and varied incisions, larger pockets, interoperative antibiotics and post operative dressage. Capsilliary contracture is the biggest problem. Placement of an implant in a submuscular phasual position has resulted in higher incidents of acceptably soft breasts, for patients the implant is the [undiscernible] pectoralis major muscle and portions of the cerebrum interior. Rectus abdominous and external, oblique phasa. Submuscular phasa implant position gives an attractive augmentation and does not cause functional impairment. Many, many women still nurse after having a baby.

All of these are [undiscernible] little ducts that carry through these, where they are little tunnels that bring the milk into the nipple. As long as none of these are cut, there is no reason why you shouldn't nurse a baby. None whatsoever.

We are going to watch a film now and go over these .....

AUDIENCE: Look familiar ... I've seen so many of these ... I was told that they have 4 rows of letters to go Monday, if we can send them ...

PAULETTE: Oh, good, they are over there working. The packet of information that we put together in the very beginning, we sent to the FDA in July, for approval, for under their regulation, at no time under any circumstances are you to write on this packet. Do not write anything on this packet.

WOMAN: When you are sending it to people.

PAULETTE: I will tell you that almost everybody has one of these on their desk open cause there is a lot information in here, that you can give to customers. But if you are sending this out, you do not say look at number, you do not write on this at all. If you would like to highlight something that is all right, you are not changing it or destroying information. Then in the letter you can say "I have highlighted what we have discussed on the telephone if you would like to read that again", whatever. So you can highlight it but you cannot write on it.

On February 4th, we received a letter from the FDA regarding this packet and I am not going to read you everything that they found wrong with the packet, we negotiated them on these issues, some we agreed with some we did not. One of the things that they didn't like on this packet is that we had a Mayo Health Clinic Letter distributed in this packet and it was dealing with breast implant, plus dealing with many other subjects in that letter, but the Mayo Clinic letter was rewrote at their request. They said about this, this article contains numerous statements which, in our opinion, are misleading to the consumer and tend to down play the importance of possible side effects of silicone. Foremost the statements we found the most misleading are the following:

> Breast implants are safe. We believe that the safety of breast implants has not yet been established. So we took that out, we did take that out.
>
> One of the other problems that they had dealt with burn [undiscernible] and is included in this packet. Tissues surrounding the implant but not the prosthesis itself has become firm, there is no risk to your health to eliminate this problem. We believe this is misleading. Surgery may only reduce the problem and it is questionable for how long. There may be a recurrence of contracture. We did not do anything about that statement, we did not change it, we did not take it out.
>
> In the patient information booklet, it's a small little booklet, in the very beginning there is a section of background information. The information given in this section describes several types of silicone implants, however, we believe this information misleads the consumer into believing that gel implants have been around for years in various and plentiful forms. In fact, many of the examples used provide are devices named solid silicone rather than gel silicone. This will be changed with the next printing of this which is ....

WOMAN: They are shipping it out tomorrow. We should have it by next Friday.

PAULETTE: 30,000 booklets. [low verbal] In the future, until the next shipment comes in we will continue to use all of these booklets until they are gone. But when the new ones come in,

it will state in the beginning that this background information deals with solid silicone implants as well as gel filled. We did change that.

> On your breakage and rupture of the implant, there has been a complication with that ... it is up at the top of the page ... they felt this statement was misleading "movement or migration of large amounts of silicone gel, however, is believed to be uncommon". There is no data on rupture rates and, therefore, the rate of movement of migration cannot be determined. It is misleading to imply that this is uncommon. We did not change that. We do believe that migration of large amounts of silicone gel is uncommon. We did not change that.
>
> This is one of my favorites, if you will notice on the bottom of each and every page throughout this booklet, "Your physician is your most important source about breast implants. You should thoroughly discuss with your doctor any questions or concerns you might have about the silicone breast implant, breast surgery and the risks associated with both." Statements such as "consult your physician" are repeated to many times throughout this booklet. While a physician may be helpful, most do not have complete information on all breast implants. This lack of knowledge is demonstrated by the large number of women who have called FDA seeking information they could not obtain from their physician. We will not change that at all.
>
> We are a manufacturer. We will tell you about our product, however, your physician has your medical history, he knows about you. We cannot tell you how our product will react with you. You need your physician to do that. You will not be changing that. Also, in the supplemental one of the things [coughing] under benefits and complications, dissatisfaction with the way it was done here by the [low verbal] one of the things the FDA wanted to know was, how long had these women be [undiscernible] implanted. We did not do this survey. We tried to get this information from the ASPRX. We would have put that in had we been able to get it. But we were not able to get it. It was a random survey and they did not have the information to give us.

WOMAN: So what is the action being taken on that?

PAULETTE: There is no action taken on that. None at all. You will find that throughout this that there is a lot of times you will refer to this booklet and it is very helpful. They had it since July and it took them until February to find anything wrong with it. So they had it quite a while.

WOMAN: So we can repeat anything that is in there. The only thing that I would caution you about using this booklet. If you are going to read something to them from this booklet, then say "I am going to read to you from the booklet I am going to send you", because I don't want you to read to them. We can do a recording that can read to them. You are a person, you are on that line, you have something to contribute.

WOMAN: But if you are going to read to them?

PAULETTE: Then say it. Another thing about this packet that I quite often tell patients in fact it is almost standard remark for everyone. You know, if you are going to send a packet at the end of the conversation, again say my name is Paulette there will be a letter on the packet is the 800 number and on the letter. Read through the packet and highlight what you have questions about, either call your physician or call me back and I'll be happy to take the time to explain anything you don't understand in the packet.

You may also want to remark to them that when they refer to package inserts in here, that these are technical, they are meant to go to the doctor. They may need to have their doctor interpret, if they cannot get the doctor then certainly call me back.

Tissue expansion is a two stage technique which increases the area of a region of tissue prior to its' use in a reconstructive procedure. It is the surgeons responsibility to perform appropriate pre-operative planning to assure that the tissue expander selected at the site of implantation will create the desired tissue flap. He has to do that, he knows his patient, we don't. Many surgeons have chosen tissue expanders as a preferable approach to post-mastectomy. There are some common aesthetic problems with tissue expanders, excessive upper pull fullness or reconstructive breast taking up to close to the clavicle, they bring it up to far, the tissue begins, the breast is to high. Deficient lateral fullness [low verbal] medical cleavage. The inability to produce a mature or even slightly [undiscernible] appearing breast has proved to be frustrating. If you have an older woman who has had a mastectomy and she is being reconstructed it is very hard to create the [undiscernible]. I have had a woman just call me and said [undiscernible] breasts.

WOMAN: What a problem.

PAULETTE: Yes that is what I thought. She did consider it a problem but you know .....

A Celastic Tissue Expander is an inflatable envelope made of high performance medical grade silicone elastomer. It is designed for temporary subcutaneous implantation after wound healing the implant is slowly inflated by a series of percertaneous injections of sterile isotonic saline.

WOMAN: What is percertaneous injection? Well I'm going to know?

PAULETTE: When a suitable skin pocket has been developed the tissue expander is surgically removed and can be replaced with the Celastic Brand Prosthesis. This product is available with either a self contained, permanently attached self sealing valve on the interior of the prosthesis or with a remote valve, valve with a tube in [low verbal] permanently attached to the prosthesis with the connecting tube. This self-contained valve includes an elevated rim around the outside of the ports and all along around the outside of this rim, so that after it is implanted you can feel where that port is. [low verbal] It just goes through the top of the [low verbal] and the tissue expander itself is a tube and the cord goes to the tissue and stays. This allows for targeting the injection port after the implantation. The remote valve consists of the self-sealing dome, it is literally a dome [low verbal] which aids in palpation. The important safety feature of both valves is the inclusion of a stainless steel needle stop in the valve which helps prevent inadvertent needle perforation of the silicone envelope to the valve. The back of this, inserts

the needle, can't go through the valve. Tissue expanders come in a variety of shapes and sizes, as you will see from the film, because they are used for many things.

WOMAN: We saw yesterday they are used for the hair transplant.

PAULETTE: Scalp.

WOMAN: Scalp.

PAULETTE: Special advantages to Dow Corning Wrights' tissue expanders are [undiscernible] the metal back needle stop provides feedback so that the position of the valve. Convenient valve collar reduces prosthesis fold over at low, low level. It is available in three shapes, in a variety of sizes, with remote or self contained valves. Fabrication of high performance valve, medical grade elastomer to provide greater resistance to tear or the propagation that ordinary silicone elastomer. Body tissue is non-reactive to .... the implant if it is sterile and uncontaminated. It comes in convenient sterile packaging. Rigorous quality control through all phases of manufacture.

There are essentially three problems with tissue expanders. Needle puncture from the surgery trying to fill, is standard, happens quite often. The expander rubbing against itself and causing holes to occur, this is something that is built over time during that period of time, it can go against itself and rub. Surgeons using them as permanent implants. [low verbal]

We never recommend that expanders stay in the body longer than 6 months. There are some permanent implantable tissue expanders but we do not make them. It is important to realize that tissue expanders often provide an alternative to flap transfer surgery for reconstruction. This flap transfer involves creating a donor site on the patients body from which healthy tissue, that is skin or skin can be excised [coughing] to that site. The post mastectomy reconstructions latimuses dorsa flap is commonly used [low verbal]. Applications for tissue expanders, the tissue expansion concept can use not only breast reconstruction but also used very creatively in [undiscernible] reconstructions, corrections of defects. The skin expander includes breast reconstructioning following mastectomy, genital breast deformities, such as polensons' syndrome, unilateral hypoplasia, tuberous breasts, reconstruction of birth breast, excision of a tumor, diabetic lesions, necroses, injuries from burns, gunshot wounds, [undiscernible] of large portions of hair baring scalp, tattoo removal, male pattern baldness. The advantages of using a tissue expander over flap is that it minimizes or eliminates the donor site. Scars, shorter hospitalization, less surgical trauma, lower costs. Improvement in flap reliability. If you are taking an expanding skin in an area where you want it, the skin has already grown there, this is [undiscernible] optimum management of texture and skin color, taking skin from another part of the body, it may not match where you are going to put it. The ability to match hair baring characteristics of skin in reconstructive flaps, skin becomes thinner after its' there or the hair becomes thinner but at least you have the hair. The absence of muscle and tendon wasting in the extremity. The expanded skin looks like a delayed skin flap, it looks good. Complications are of the tissue thinning or sloppy can occur, poor vascularization. Vascularized skin, if inflated before the site is adequately filled can cause necrosis and the skin will die. With radiation treated skin, a lot of times when you hear women talk about their implant kind of

pushed there way out of the skin most of the time those are cancer patients who has gone radiation and reconstruction. The skin is already thin, the skin has been damaged by the radiation and now they are trying to put an implant in or expander in and the skin is literally stretched so much that there is no more blood vessels running through that skin and the skin dies. If it is inflated before the site is adequately filled with radiation treated skin, expansion under a scar or placement in the lower third of the extremities which is probably due to vascular compromise. It is not like the blood can flow in there. Fluid accumulation at the site can be a complication, use of drains often prevents or relieves this condition. Testular contraction can also occur with tissue expanders. For breast reconstruction, some surgeons felt that submuscular placement of the expander minimizes this effect. Inflation of the prosthesis is spontaneous can be due to severe impact to the skin expander in [undiscernible]. It is [low verbal] due to creasing caused by placing a folded empty implant which is not uniformly expanded when felt in [low verbal]. Accidental puncture of the envelope with a needle point when filling. Migration or rolling of the expander if it is not sutured in place. Local pressure and/or pain in some cases. Urethema which usually disappears when the skin expansion and reconstruction is completed. The scar is visible during expansion.

Infection. Early reports were generally recognized as being caused by poor patient choice. Open ulcerative sores or any diabetic [low verbal] infection as a complication is non-existent or at a very low level to that.

Alternatives to tissue expanders are skin flaps and grafts. In the past surgeons used flaps of tissue from the patient to repair defects. This created problems, since it required the surgeon to then cover the area where the flap had been removed. Where creating more sites for infection then because [coughing] this procedure is still done for defect reasons that is not suitable for tissue expansion. The best way to gain a clear understanding of this procedure is to be [undiscernible].

Indications for tissue expansion may be to cover defects after trauma, skin lesion removal, to create hair bearing surfaces in male pattern baldness, to prepare the female breast area for implant insertion, usually after a mastectomy. There a couple types of tissue expansion interoperative, which is done during surgery, when the skin lesion is removed it is a single stage procedure, it is all done at one time. That is what he will do. It is also a staged expansion, and when this tissue expander is put in place and gradually expanded over time, and surgery is performed to remove that tissue expander and the excess tissue is brought forward to cover the defect.

WOMAN: What is the term of that procedure?

PAULETTE: Interoperative. Means done at the time of surgery.

The concept with tissue expansion is that human tissue can expand easily and a good example of that is pregnancy. Since this is possible we can actually create tissue expansion and use this excess tissue to cover tissue defect. The excess tissue maintains good color appearance and the feelings since the blood vessels and nerves and hair follicles remain intact. Same skin, same area. Okay.

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TAPE 4 SIDE B

PAULETTE: .....are over [undiscernible]

What I am going to do is read to you a small synopsis of all of the complications. As I go through it I will try to also tell you some typical questions you will get in these areas. Later on this afternoon we will talk about, before lunch we will talk about typical questions and answers. And I have written many of those down so we'll really talk about those. I will also point out to you in this hand out here what are the top areas of concern. Later on we'll go through the package insert after this, which covers these things in a lot more detail. As a matter of fact, I may change around monitoring and packing inserts so you don't get them both one after the other.

The first complication is asymmetry and asymmetry is not being even on both sides. It is natural to be asymmetric and most women are. Some of the causes for this with implants is a preexisting anatomic asymmetry. In other words, before the implants were put in you were already anatomically incorrect. The incorrect choice of an implant size or shape, the surgical technique can also cause this, contracture can cause this, seroma or hematoma, breast dysplasia post op, discrepancy in the loss of development between the sides or ruptures in which case, of course, it is recommended that the implant be removed. To correct any of these defects surgery is required. It is not something that can be done without surgery. Very few questions on asymmetry and when they do come in, it is usually dealing with capsilliary contracture because, as you will find out, the breast can become hard and misshapen and it usually does deal with that. Totic breasts, variability in skin elasticity and muscle tone can contribute to totic breasts. Tosis can occur in augmented breasts just as it does in non-augmented breasts. It is gravity, it is a natural aging process.

Breasts in nipple or aureala sensation, loss of sensation is commonly reported after undergoing breast surgery. The more extensive the surgery, the greater the probability of loss of sensation. The return of sensation varies among patients and, in some cases, it has taken it as long as several years to come back. There are also reports of permanent loss of nipple or breast sensation and a cold, itchy breasts. The breast areas found in implantation and again, you know I refer to Jennie Jones, she has had five surgeries all through the peri aurealar area and has lost all sensation and all feeling in her breasts.

WOMAN: And we don't doubt that after seeing the film ... after the first time.

PAULETTE: It's very obvious isn't it. After five times it doesn't surprise me at all, that she has lost sensation. [coughing] You know we do get some questions about sensation, and the answer is simply that have you spoken to your doctor about this? And, what does he say? Certainly we have heard it in cases where years later the sensation will return. Usually, it does not take that long. If it is 6 months after surgery and you still do not have sensation back and

you have not seen your doctor, then you should go talk to your doctor. Again, he is the one that knows this woman.

WOMAN: It would seem that it would be one of the things that he or she would tell her. Surgery ..... [talking at same time as Paulette]

PAULETTE: However, you have to realize that not every one does. That some surgeons judge on what they tell their patients on the patients themselves. How much can you tell them. You know, if she has cancer or something, that she is being reconstructed, she's going to die in six months, do I need to tell her all these things. Understand, we have to come from his point of view too. I don't know. Some we know are very good and sit down and go through everything. And, again, it may be something that comes out of this. In Maryland it is a State Law that you must tell every complication ... so it may come out of this ... that it will be more of an issue now than it ever has been previously because of the whole issue, the doctors will be much more responsible about reporting everything.

WOMAN: [talking at same time as Paulette]

PAULETTE: Breast region pain has been reported as an expected occurrence following breast surgery, as you can see why. This also can be associated with capsilliary contracture.

Interruption of surgical incision wound healing. Causes are infections, fluid accumulation and lack of drainage. The woman again that we talked about yesterday, that I had dealt with so many times in New York, there was no drainage and to have an implant implanted that may be 250 or 300 ccs and then have 700 ccs of cirrus fluid to be drained from your breast, that woman had to have been very, very uncomfortable. Very uncomfortable.

WOMAN: And her appearance must have been like a big balloon too.

PAULETTE: That's right. Talk about stretching the skin. And that woman had had a mastectomy and radiation treatments and necrosis, she had a lot of problems.

Usually the pain that we hear about on the phones is connected with autoimmune diseases, joint pain, that kind of thing but we'll get into that later on here today. But there is not a lot of talk about pain. Certainly, if someone says my breasts are just terribly painful, one of the things you may want to ask is when did you have your surgery. If she only had it a couple of days ago it doesn't surprise me that it is painful.

WOMAN: Doesn't surprise me. Especially after seeing that movie.

PAULETTE: Interruption of surgical incision wound healing, boy, usually something that is happening there with the fluid accumulation or with the drainage, that certainly comes into play there. Hematomas. To tight of a closure. To large of an implant with the pocket that was created for it. Contamination of the suture wound, I believe in New York that was part of her problem too, the suture wound had been contaminated and they used the same incision site several times. Abscess of the sutures. Improper support, pressure on the wound. All of those

things can cause that.

A skin slopping or necrosis. This is a breakdown of the skin covering the implant. Some of the causes of this are inadequate circulation where the skin is very thin over the implant or the implant is to large, thereby stretching the skin and making it thin, cutting off the blood circulation to that skin, cutting off the life supply actually to it. It can be attributed to trauma. To the skin interoperatively, during surgery some damage was done to that skin so that the blood supply can't get to it. [coughing] Anti-inflammatory steroids, as I said yesterday, this is the common practice in these surgeries and it is not any more, and it would cause what was known as the blue dome effect where the top of the breast would literally turn blue.

Skin deterioration or breakdown. The resulting necrosis can be the implant actually coming through skin. Some instances, also tissue expanders by the way, actually coming through the skin. Some instances where this has been reported are where subcutaneous placement of the prosthesis was used for reconstruction in cases of genital amastisis, subcutaneous mastectomy and cancer mastectomy, especially, where radiation has occurred and more than likely anytime that someone talks to you about necrosis, they are a mastectomy patient and have gone through radiation. Every one that I have ever dealt with has been that. If someone says my implant is coming through my skin ... excuse me ... incorrect size, inappropriate location of scars and misplacement and/or migration of the implants. These complications are usually, iatrogenic or surgery in nature. Surgeons performing this type of surgery should be familiar with currently acceptable techniques. That holds for measuring the patient, determining the correct size, and performing the surgery. Implants generally cannot be repositioned following closures. Surgical revision would be required if the implant is misplaced or displaced. Certainly, I have heard many times on this, we heard several yesterday that one went up, one went down. I have heard women say my implant is moving into my armpit. That happens, that definitely happens. The answer to those patients are that they have to see their physician. Have you ever heard of this happening? Certainly, I have heard of it happening. I think that you will need to see a doctor. If your implant is misplaced like that you need to see your doctor. Understand also that with capsilliary contracture, an implant can appear to be misplaced. Because capsilliary contracture can occur in one breast and not the other. One breast can rise and become hard, while the other breast does not and it appears as if one is going up and one is going down and it's really not. The capsilliary contracture on that side is causing that to happen. Because surgical revision is required the only answer for these people are to see their physician.

Again, if they do not have a physician or they have moved from where they used to live, they have this done, you know, those kind of things, then certainly we do have the outlet for them through the ASPRS, or the American Academy of Plastic Surgeons. We have 800 numbers that we can give to them. What these people do is give them a list of doctors in their area. They don't talk to them.

Wrinkles, folds or knuckles in the implant shell. Surgeons have reported that in some patients wrinkles, folds and/or knuckles in the implant shell may occur and be visible and/or palpable. Wrinkles, folds and/or knuckles are a possible outcome especially if one of the following conditions exist:

> The patient is thin and small framed. Little or no subcutaneous fat.

The MSI, the textured implant that we had out what they had done to help alleviate this problem is that they did a moderate fill on that, they took it in and filled it a little more than what it normally would be filled. Of course, now we don't make any implants so that is beside the point.

> There is no breast tissue or the breast tissue is sparse. The overlying tissue is of poor quality.

An example would be a post-partem patient with elastic skin or mastectomy reconstruction in the patient. The placement is subcutaneous, behind the mammary gland. The implant is to large for the patients frame size or the size of the pocket which was created. Capsilliary contracture is present.

And I want to tell you what a knuckle is. I am not sure you know what a knuckle is. Like the fold is on my jacket right, the end of this fold right here, that is a knuckle. That is what a knuckle is. Okay. Knuckles can rub against the skin and cause necrosis because of the rubbing, rubbing, rubbing... It has been noted that they will disappear or it has happened that they will disappear all the time, also. You are putting this smooth implant into a pocket, as you are inserting it, folds can occur, knuckles can occur, so we have to be careful of that. On these wrinkles or rippling are commonly seen in the clavicle or below the collar bone, which is this part of the breast, it is usually seen right there.

On the program that I saw Jennie Jones on and [paper noise].. she has what she says is silicone there, and it may well be but I don't know. But it appears to look like a wrinkle.

Folds with associated knuckles, at the ends of the folds are commonly seen in the lateral to medial [paper noise] which is on the insides of the breasts. This area. Surgery may be desired by patients with wrinkles or folds, sometimes these are reported to diminish with time. It has been reported that folds have led to thinning and erosion of the overlying tissue. This, of course, would require surgical removal. Once in a while you will get a call about wrinkles and, again, those are times that you may want to say, "What is your frame? Are you thin?", and nine times out of ten they will be thin. This is something they have to go back to their doctor about, it is something that is surgically corrective. If they want to know about we certainly can talk about it. We can talk about anything that is in here also and tell them what we know about.

WOMAN: Paulette, when you said we can ask if they are thin, I thought we weren't supposed to ask them questions?

PAULETTE: But when you are trying to get to the rut of the problem and what they are looking for. The questions, that I really would prefer that you don't ask is what is your name, where do you live, what is your phone number, that kind of thing.

WOMAN: So questions just to get specifically around ... details about ....

PAULETTE: About what .... because sometimes you know, understand that you are coming into this conversation with a lot more knowledge than they have. So you need to try to pinpoint exactly what they are talking about. Because if they are talking about a wrinkle, you don't want to be talking to them about capsilliary contracture. It is the wrinkle that is their concern. So you need to really pinpoint down to what they are talking about, get some idea about her, is she that thin that is possibility the problem, is that possibly what's occurring? And, again, the answers to those things are certainly I have heard of women who are thin that have problems with wrinkles with their implants. That possibly is what you are experiencing. You may want to see your physician about that. Because she may come in to you and say, I just feel this lump there and it's long, and it's thin and you are trying to think about what could this be. Is it rupture and the implant is leaking, is it a wrinkle ... so you are going to have to get some knowledge from them. Again, you are not there to give medical opinions, you are not there to diagnose their problems ... just trying to pin down and give her some information. As a matter of fact, a good answer to that is possibly what you are experiencing is a wrinkle and I will send you this packet with information and I will highlight in the package insert where it talks about wrinkles, read it over, take it to your doctor and discuss it with him whether he thinks it is or not. He is your best source.

Palpable Implants. Surgeons have reported being able to palpate implants. This can occur in a patient where the implant is to large for the pocket, where the patients frame size, also, where there is thin, tight overlying tissues, when the implant is placed subcutaneously and/or when contracture occurs.
Okay. Now the infamous capsilliary contracture. Capsule formation and contracture, this is a post-operative formation of fibrous scar tissue which encapsulates the implant. It completely and totally surrounds the implant. You will hear reports of my implant group to my chest wall. It is completely and totally encapsulated with scar tissue.

WOMAN: ....[undiscernible] attached to the wall?

PAULETTE: No. Scar tissue just surrounds it but it doesn't attach itself to the wall or to the mammary gland. Certainly, it's there.

WOMAN: Probably feels like it.

PAULETTE: It probably does feel like it. Yes. This is a normal psyiological reaction to any implantation of a foreign object. It does not matter if it is a breast implant, if it is a pace maker, if it is a sliver in your finger ... your body is going to do the same thing. If you have ever had a sliver that you haven't gotten out right and it is hard around there, scar tissue forms around there. So foreign object, the body doesn't know what it is, has to close it off. And as Bob talked about, has to fill in that hole, there is a hole there and its' natural reaction is to fill it in and close it up. Capsule formation occurs to some degree in all patients. Each patients capsule varies in degree from thin to very thick. I think Bob also talked about women who have very heavy scars and some women don't. And there is no way to know before you implant an implant, if this women is going to have capsilliary contracture or not. We don't know if it is going to be in one breast or both breasts. And, yes it may reoccur. That is the biggest complication with implants is capsilliary contracture. Capsilliary contracture occurs when the

scar tissue shrinks around the implant and squeezes it so that it feels firm and, in some cases, hard. No one knows why women develop capsilliary contracture and others don't. What I want to tell you about capsilliary contracture [coughing] it is a smooth implant and it grows like this around it and it is just layers and layers and layers ... of scar tissue. All the fibers in it are growing one way, growing around it and as it grows it pushes on the implant. The implant itself does not become hard or scar capsuled. Scar capsule is what becomes hard.

WOMAN: It is putting pressure ... what about the process of rupture then?

PAULETTE: It has never ruptured.
Contracture does occur in various degrees. It occurs in everyone understand. Encapsulation occurs in everyone. From barely detectable to a very hard breast and Dr. James Baker in Florida, devised what is called the Baker Scale, and Baker is absolutely natural, you would not know the difference, you can't tell the difference. The Baker II is minimal somewhat firmer than normal. No complaint, it is not hard but it is firmer than normal. Baker III is moderate the patient can feel the firmness and it is noticeable. Baker III is a degree that some women like. The breast is upright, it is projected more, they have no complaints about that, some women like that. Baker IV is severe obvious from oxidation. It is hard, it is displeasing in appearance, it is painful to the patient, and you can tell some man made this name up, it is referred to as the door knob effect. No comments.

It can be severe enough to be bothersome, painful and it may cause deformity as it pushing down, the breast may become deformed. I believe we saw some pictures yesterday that looked horrible. Who would want their breasts to look like that. It can occur on one or both sides and to a different degree on each side. It can develop any time even years later. Although, it is most likely to occur in the first several months. If it is treated, it can reoccur. The other think I want to show you is that with an MSI implant [coughing] implants out there from other manufacturers. The MSI has pillars on the surface like this, when the scar capsule begins to form around the pillars the theory is that it will grow in between here also -- not into the implant but into the spaces between those pillars. It will also grow around it ... but because it is growing between these pillars it is breaking out in continuous growth of that fiber and, thereby, stopping capsilliary contracture from happening.

The theory is looking pretty good so far but, of course, now we aren't doing it any more. But, in the women that have had it since 1990, the contracture rate is very, very low, very low. So it is palpable. And that is the same thing goes with the other implants that are out there from other manufacturers that are [undiscernible]. It actually creates pockets so that the fibrous scar tissue doesn't grow all one way. Ways of treating capsilliary contracture is closed capsulatomy, you will get a lot of questions in this area. I will tell you this is the number one area. One of the number one area is capsilliary contracture, be sure you understand it. If you have any questions, do not be afraid to ask.

Closed capsulatomy is the procedure where the doctor tries to forcefully break up the scar tissue.

WOMAN: I have seen pictures of that. It looks really brutal.

PAULETTE: By squeezing the breasts ... Jennie Jones, I hate to keep commenting on her [coughing] but she had had to be literally put to sleep to do it. I talked to patients who have had been sedated before, taking pain medication several days afterwards. This doesn't always work, it can result in bruising, bleeding and rupture of the implant. Doctors have been known to dislocate their bones doing this procedure. I have heard many people, and don't be surprised at what you hear in this area of closed capsulatomy. I have heard of women who said, he literally straddled me on the table to do that, with such force, he beat on my chest, I mean there are many, many things that come. Normally, and you will hear this time and time again, he popped my breast, because when they break up that scar tissue there is a popping noise. You can hear that scar tissue break.

WOMAN: What happens to that scar tissue? Does it then dissolve.

PAULETTE: No it does not.

AUDIENCE: It still exists.

[all talking at once]

WOMAN: Will it fill in again.

PAULETTE: It can reocur. Yes.

Dow Corning does not recommend this procedure nor do other manufacturers of the implant. I will tell you that if a woman is talking about rupture, 9 times out of 10, she will tell you she has had a closed capsulatomy.

Also, understand that during a closed capsulatomy, if he is forcefully breaking up that scar tissue, and you know what it takes to do that, and he ruptures that implant, that does not mean at that point that all that gel is going to go all over. This may be a point at a future point down the road, this gel is going to start leaking and he has broke up the scar capsule so now the gel can escape also from the scar capsule. But gel is not something that just runs out like water. As a matter of fact, if there is a puncture in an implant and you squeeze it gel will come out but if you release it will go back in and gel does move at such a slow rate that it can not be reported, a number cannot be put on it in the laboratory. You can't see it moves an inch every three months. It moves so slowly and in such minute quantities that it cannot be calibrated in the laboratory. And they have tried, I talked to Bob LeVier, and they have tried to do that. An open capsulatomy involves surgery, where the surgeon removes the implant and he will make many lacerations in that capsule to break up that continuous fibrous growth there. He may even remove part of the capsule and take some of it out.

Implants are put back into the breast pocket. Now here is an interesting thing. Of course, Dow Corning has always recommended that if you are removing an implant do surgery to remove a closed capsulatomy or whatever, that you put in a new implant, you do not reinsert the old one. However, you will hear many times about the old implant being put back in. They took it out cut the scar capsule around the old one and put it back in.

The woman in New York, at one point in one of her surgeries, they took the implant out because of the incision line wasn't healing, they took the implant out in the Emergency Room put it in a saline solution, opened her up, cleaned up the pocket and put that back in out of the saline solution and closed her back up again. This woman also worked in a hospital and worked with the plastic surgeon that did this, but he was not a plastic surgeon that did breasts so he wasn't experienced. Again, they must know the acceptable technique, what is going on in the field today, and if you are not experienced ... and I have no problem with telling women you should ask the doctor, how many of these have you done? can I see pictures? Plastic surgeons are notorious for taking pictures. They take pictures all the time. They always do it. It doesn't mean they necessarily have the patients head in it, but it is a picture. Do you have anybody I can talk to that you have done this to? You know, women need to know that they can be informed, that they should insist on being informed. I think sometimes in our society we tend to have that, it's okay dear just go home, pat her on the head and send her on the way. They need to be informed.

Implant rupture. Rupture can occur inter and post operatively. Sometimes the rupture can occur for no apparent reason. We at times hear the term spontaneous rupture. There is no such thing. The reason for a rupture may not be apparent, but there is a reason. We may never know the reason. We may never know why that implant ruptured. We may never know that. But there is a reason. Implants do not just explode in the body, they just do not explode in the body. You could even have a rupture and not know it and that is referred to as a silent rupture. If your implant is ruptured but your scar capsule is in place, you may never know that you have that rupture. Because that scar capsule will hold that silicone gel in the contained area. Of course, this is another big one as you can imagine. One of the other things I want to say about implant rupture and silent ruptures is that, we have heard many women say that the doctor took the implant out and envelope was completely gone. It is impossible for the envelope to disintegrate in the body,number one. Number two, what happens is and what we know happens, is that the implant will literally turn itself inside out and they will send that back to the lab here or wherever and they will find the envelope in among the gel but it is like turned itself inside out, but it is there.

WOMAN: When it ruptures?

PAULETTE: Over time it will do that. I am just telling you that because you will hear somebody say and the envelope was completely gone, there was no envelope at all.

WOMAN: It was inside.

PAULETTE: Now understand you might not be able to share everything you know but you need to know what you are talking about and where you are coming from.

If you experience changes in the size or shapes of the breast or experience trauma to the chest, a mammogram may be able to detect it. We certainly do not recommend, if somebody says to you I think I have a rupture, we certainly don't say you'd better go have a mammogram. That is practicing medicine and we cannot do that. But for your information, mammograms can detect it. If it is severe, it will show on a mammogram. However, if it is a pin prick, it will

not. [undiscernible] there is an indention there, it is not a whole implant any more, you can see it. If it has started to leak, because silicone is radio opaque, it appears as a white cloud, you can see it on a mammogram, we can threads where the silicone has started to leak out.

The scar tissue which encapsulates the implant could keep the gel from spreading. If that scar tissue is not ruptured it can hold the gel inside. Movements of large amounts of gel are believed to be uncommon. Gel moves at such a slow rate, again, that scientists cannot assign a number to it in the laboratory, they cannot calibrate how slowly it moves. We, of course, recommend the removal of rupture implants. Ruptured implants are not fulfilling the job they were meant to. If they were ruptured they need to be removed. There's all kind of things that come into play here. A woman will call and say my implant is ruptured. Have you seen your doctor, should be the first thing out of your mouth. If they have not certainly talk to her about rupture but encourage her strongly to see a doctor. She should see a doctor and you will get all kinds of things from "I don't have the money to see a doctor to I can't get out of work to see a doctor", all of the excuses that you hear all the time. I think that we need to remind them that this is your health that we are talking about. Sometimes you have to come up with the money to see a doctor, you know, the most important thing is that you are taken care of and a lot of times if you express to her that your concern is her and that she does take care of herself that together you will work through this. See the doctor, let me know what he says, what is his diagnosis, what does he tell you to do, let's at least get that over first and then we will work on the rest but let's see a doctor first. I think sometimes women have a tendency to put themselves last and everybody else first, that is the mentality that we fall into and she needs to know that she needs to see a doctor if she is suspecting a rupture. She should see a doctor.

Foreign body reaction. If an implant ruptures and the surrounding scar capsule also ruptures small amounts of silicone gel may begin to move out of the pocket created to hold the implant. When this occurs the body sends what are called macrophasas, little Pac Men, tiny, tiny cells. Macrophasas are part of the immune system and can travel throughout the immune system. They can go any where in the immune system. They send the macrophasas to this area to pick up the minute amounts of silicone and take it across the tissue plains to the nearest lymph nodes. The nearest lymph nodes to the breast are in the half moon shape over the breast running under the arm. They will come across the tissue plain leaving gel, of course, on the way. I mean we have heard reports of gel being in the tissue plain definitely. Because silicone is biologically inert, the lymphatic system cannot break it down and pass it on through the body. The lymphatic system is created to break down infections, to break down virus, to carry them out of the body through urine, fecal matter, to get it out of the body. It cannot break down silicone -- it is impossible. The silicone at the sites of the lymph nodes will, in time, become surrounded with scar tissue and form what is called the granuloma and a granuloma is a site where many macrophasas have come together and formed a lump. These lumps are usually microscopic. Sometimes they will get big enough so you can see them, I should say you can feel it, you might not see it. And that is all they are, are macrophasas containing silicone. Small lumps or granulomas will always appear at the site of the scar capsulated silicone, these lumps must be biopsied because there is no way of knowing if they are silicone or another disease. A doctor cannot look at that lump and say, that's not cancer don't worry about that, or that's not whatever, don't worry about that. You can't just look at it and know. They have to biopsied.

If a ruptured implant is left in place, the following complications may occur: enlarged lymph nodes, scar formation, inflammation, granulomas forms body reaction, nodular formation and other difficulties may result. Migration of silicone gel to adjacent or other tissues may occur. If you have a ruptured implant it needs to be removed.

I'm trying to think of some other questions that you may get about rupture.

How do I know if I have a rupture. My first remark to that usually is do you do regular monthly breast exams. If she says yes I do, then you would feel a change in your breast, you would know there is a change there. That's why you do monthly breast exams to detect changes. Understand not all women do them. Is there a change in the shape or look of your breast. Is there a reason why you think you have a rupture. Have you had trauma to the chest, have you done something that there may be a rupture, again, the thing about ruptures is that they have to see their physician. You have no way on the other end of a telephone to know whether that implant is ruptured or not. If you were on the other end of the telephone, you probably would not know whether it was ruptured or not.

WOMAN: Would you recommend that they go get a mammography exam?

PAULETTE: No because that's practicing medicine.

WOMAN: But you can say sometimes a mammogram...

PAULETTE: You can say your doctor may ask you to get a mammogram to check that out.

WOMAN: Can we give the information that a rupture or a leak could be discerned by a mammogram? Is that practicing medicine?

PAULETTE: You can say that, but if you say that, I would like you to also include that "if it is severe it will show, if it is a pin prick, it will not show up".

WOMAN: So if you put that out there leak you have to say severe leak.

PAULETTE: Pin prick is not going to show on a mammogram, and that is fine, you can tell them about mammograms that this is radio opaque, that it appears as a white cloud on the mammogram. If there is a severe rupture you will see it. If it is a pin prick you will not.

And, please do ask if you have any questions at all. Later on I have some typical questions and answers. Possibly at the end of the day, when we are all done, if we still have time, you can may be shot some questions at me that you might think of yourself and I will try to answer them as you might answer them on the telephone.

Infection. When infection occurs and is associated with an implant site and appropriate regimen of treatment should begin. If the infection cannot be brought under control then we recommend the implant be removed. I have very seldom gotten any questions, may be one or two, in all the months we have been on, about infections.