Hematoma. This is usually a surgeon oriented problem through failure to perform meticulously [undiscernible] which is the principle measure for prevention. If a doctor chooses evacuation as a form of treatment, care should be taken that the implant is not ruptured.

WOMAN: Can you define hematoma?

PAULETTE: Hematoma is blood clot. It is a gathering of blood in that area. If the doctor is going to use hemastatis to get in there and drain it, he could rupture or pin prick the implant at that time. It may not rupture the implant then but it certainly interrupts the integrity of the shell of that implant. And, at some future point in time, there is a weak spot where that needle has pricked that, it can cause a rupture some where down the line. So he has to be very careful when he goes in there. Hematoma, I have never gotten a question on.

Cirrus fluid accumulations. This occurs occasionally with the surgical placement of any mammary prosthesis, it is accompanied by pain and swelling. Cirrus fluid is a thin watery fluid, as you might see with any movement. It is reported to occur more often in textured implants as part of the normal wound healing as compared to smooth surface implants. This complication can also occur as a part of trauma. Just as any time that you traumatize any part of your skin where that thin watery fluid comes up, that is cirrus fluid. And that can happen also in the breast area. If aspiration is used, the surgeon must take extra precaution to avoid rupturing the implant. He is going to stick a needle in their again, there is a chance. There is a chance that he could do that to the implant when he is suturing the closure of an incision site during surgery.

WOMAN: Can it happen in the perirealure?

PAULETTE: It happens more often in the mammary. But it can happen in the perirealure too.

WOMAN: I noticed that they did [undiscernible] when they suturing off in one of them.

PAULETTE: Actually in both, the axillary obviously is a little better when you are not suturing any where near the implant [coughing] as you are you must be careful because if you, as I said, the pin prick is not going to make a rupture occur immediately, but it has interrupted the integrity of that shell, it has created a weak spot and there could be a rupture some where down the road.

WOMAN: What is the occurrence rate of a surgeon himself in stuffing the envelope in hitting it with an instrument?

PAULETTE: I don't have a percentage but I ....

WOMAN: It does happen?

PAULETTE: It does happen, oh yes.

WOMAN: Or taking it out of the sterile package, where somebody used a knife or any thing

to open it?

PAULETTE: That's right. I will tell you in our analysis, in litigation, in claims, when the implants are brought back, that these people are fantastic, may be they can tell you if it is a suture hole that caused that implant to rupture. They can tell you what made that implant rupture. If there is a tear where an instrument hit it, they can tell you.

We had one patient who wanted her implants out, who had had a mastectomy and in the beginning of all of this wanted her implants out and her doctor said there is nothing wrong with you. Surgery is a risk and I am not going to put you under to take implants out when there are no problems, you have no problems and there are no problems with those implants. At that time, her implants were not ruptured. This women took a long needle and put it through her nipple and ruptured the implant five times. I have ruptured the implant and now you have to take it out. She had no feeling.

WOMAN: She had no brains either.

WOMAN: Yes. But he wasn't giving her a choice. He was ruling her, he was telling her he couldn't.

PAULETTE: She could have gone to another doctor. But I agreed with him. If you are not having a problem -- it is a risk to go under anesthesia.

IMPLANT HOTLINE PROGRAM
TRAINING SESSION
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TAPE 5 SIDE A

[undiscernible]

AUDIENCE: Yeah to do what you would do that. If you would just do that to yourself. Why not just take a gun.

PAULETTE: She felt she had to make a decision, but apparently she felt she had no options.

I was going to talk to you about creating a [undiscernible] about reconstructive surgery. Of course, there is no feeling in that nipple that they can recreate. And, I will tell you that many women do not care to have a nipple recreated as long as they have the mound that is all they care about. They don't care about the nipple. You can have a nipple tattooed on, on the skin itself. They can also take skin off the labia and that is already darker colored skin. What they do is take a strip of skin like that and then they fold this over, this over, this over, this over and pull it tight and then they make a nipple, they just graph that on to the breast. To make it the dark brown, it needs to be tattooed. So this woman had no feeling in her breast whatsoever but it was still, it was a drastic step to have that removed.

Cirrus fluid. Sometimes you will get questions on that. Some doctors don't perform drainage as they should. And, again with an MSI we know that this happens more often, or textured implant I should say, because there are other textured implants out there than the MSI.

Calcification. Doctors have reported calcification of the surrounding tissue. In medical journals it has been referred to as heterotrophic ossification, which is the changing of tissue to bone. In some instances heavy calcification results in discomfort, firmness and may require the removal of an implant. May be one or two questions, I never give great detail. Usually when you hear about calcification, it is my doctor told me that I have calcification. There is not a lot of controversy about that. Not a lot of questions on that.

Gel Bleed. Gel bleed is the passage of small quantities of silicone fluid, not gel, from the inside of the implant through the outer shell. Quantities are minute and there is no scientific evidence that gel bleed causes harm to the body.

WOMAN: Would gel bleed be like when you are handling an implant and that kind of slimy feeling as when you put hand cream.

PAULETTE: That's gel bleed.

WOMAN: You are saying silicone fluid versus gel.

PAULETTE: That is right it is not gel.

WOMAN: So then the statement that there is no scientific evidence that the silicone fluid bleed.

PAULETTE: No. It is called gel bleed.

WOMAN: Okay.

PAULETTE: It is not gel. But it is called gel bleed – it has always been called gel bleed. To give you an analogy of what that is like, it is like when you are exercising or working in your garden or cutting your grass, and little beads of sweat begin to form on your forehead, upper lip or whatever. That is how it bleeds. It doesn't bleed ... It sweats, that is a visualization that you sometimes need to give women and you don't have to state it that way, but that is what it is -- It is sweat, it is not bleeding. Especially, with everything that is going on they get this picture of bleeding out of there.

WOMAN: Or sweat, visual discernible drops, but if I think of when you lay an implant on the table you have this little oily spot, that would be like what you are talking about.

PAULETTE: This is really the answer for gel bleed. Please understand that gel doesn't bleed the elastomer envelope. The molecular make up of gel is such that the molecules are to large to enter into organs such as the heart, the lungs, etc. What actually leaves the envelope in the process called gel bleed is some of the fluid that the gel is made of. This fluid moves at such a slow rate that scientists cannot assign a number to it. It also moves in very minute quantities. Very small cells called macrofashes, pick up these minute quantities of gel, of fluid, I'm sorry and carry it to the lymphatic system. We know that one of the areas that the macrofashes take the fluid to is the lymph nodes which are located in the half moon shape over the breast running into the auxiliary area under the arm. When the macrofashes come together in a group, it is called the granuloma. Granulomas are usually microscopic, however, they do have to be biopsied, there is no way to tell whether a lump is cancer or not cancer. Your doctor has to biopsy that. Okay.

You will have to judge talking with this woman, how much of this she can understand, and how you can tell this to her in a way that she can understand. You may ... As a matter of fact this is ... you will get this printed out, somebody has this written up. I wrote it and I think Wendy typed it. So somebody has it written out.

I think that when you explain gel bleed to someone you need to say, do you understand? do I need to talk to you more? Do you know what I am saying. Say to them: Do you understand what I have told you? Do I have to cover that again? Can I explain something that I have said to you? so that she understands what you are talking about.

I will tell you that gel bleed, the bleed rate is 90% less in [undiscernible] implants. After 1982, when we began putting florasilicone barrier in, the gel bleed was 90% less. That is not a statement that I would quote on the phone because if you have somebody "yeah, well I had mine in 1977, does that mean that I have tons of gel bleed going into my body?" ... because that is what will happen. You have to listen to what they are saying and answer the questions they are asking you. I would certainly encourage you at the end of every conversation to say, "is there

anything else that I can answer for you?", because when you get your call from FDA, which you will, cause they monitor this phone, when you say "is there anything else that I can answer for you?", you have covered yourself with the FDA. You are not saying, I'm only giving out selected information. You are asking them if there is anything else that you need to cover with them.

WOMAN: So the FDA is into these lines.

PAULETTE: Oh, yes. We'll talk about that when we talk about monitoring. No we don't tape them.

WOMAN: Is it like a wire tap, or what.

PAULETTE: What they do is, literally, call in and start questioning you, and I will tell you that most of the people ... you'll just know. You'll get a feeling for that. Because when you are talking to patients you almost know, this isn't a patient. This is not normal, this is not things that happen all the time. If you have a gut feeling that says no, then it is probably somebody monitoring you, it may not be the FDA, it may be somebody from Dow Corning. We do that also. I walk around and monitor. So we will talk about that when we talk about monitoring.

The thing of that is there is answer for capsilliary contracture, there is an answer for rupture, there is an answer for cirrus fluid and calcification and gel bleed, and as long as you give the same answer, each and every time, you have no problem with whose calling. You have given the correct answer. There is no problem if it is the media, if it is a lawyer, if it is FDA, if it is Dow Corning monitoring you or it is me walking around. [coughing] If you give the same answer, as long as you give the correct answer.

Immune Response. This is talking about autoimmune diseases. The bodies natural defense system is called the immune system. The immune system attacks those things foreign to the body including any kind of implant made of any kind of material, metals, plastic, teflon, silicone, anything. There are several diseases that can occur when the immune system goes awry. This includes connective tissue disease.

Connective tissue is in the human body to bind tissue and organs together. Examples of connective tissue include skin, bones, cartilage. The number of cases of connective tissue disease reported in women with silicone breast implants is small and likely within the number expected by chance alone. Diagnosis is difficult and usually by process of elimination. Our research so far shows no correlation. We are conducting further studies and the following are some of the connective tissue diseases that are being discussed today:

Scleroderma which is a hardening and thickening of the skin and usually appears on the arms and legs first. Very small patches, very slow progressing disease. It takes years and years for this disease to progress. It can be a life threatening disease. It tightens up the skin. The skin appears as leather. I have seen women whose hands are bent and cannot move their fingers

because of this disease. The reason that it can be life threatening is that it can attack your vital organs, make them hard, make them non-functional.

WOMAN: This is the test that we are doing at U of M now?

PAULETTE: Yes. This is the epidemiology that is going on at the University of Michigan.

Rheumatoid Arthritis which is the swelling and inflammation of tissue around the joints.

Lupus. Lupus is a rare disease. It is very rare. It is characterized by inflammation and damage to connective tissues of the body. This can occur in one or several sites at one time.

Again, Scleroderma task force sponsored by the American Medical Association has concluded that there is insufficient evidence that breast implants cause connective tissue diseases and there is no reason for surgeons to discourage women from considering breast implants or to suggest removal of implants in women who already have them. Both the FDA and the Scleroderma Task Force of the American Medical Association have concluded and reported that there is no definite diagnosis for human adjutant disease. That the term is non-descriptive and that it's use should be avoided.

In this packet, under connective tissue diseases, it talks a lot about the three main ones that we are looking at there is scleroderma, [undiscernible] and lupus. But I might draw you attention to how [undiscernible] connective tissue diseases like scleroderma and lupus are quite rare. The Arthritis Foundation estimates that the number of new cases per year of scleroderma in this country is about 10 per million of the population. Scleroderma like other connective tissue diseases are 2:4 times more common in women than men and it increases with age. This suggests that there are may be from 70 to 90 new cases of scleroderma in this country per year. Now if you take the number of 70 to 90 women that have implants, you have brought that number down even more. That is why we had to pick at the University of Michigan. They are doing the whole state, any woman in the whole state, that has Scleroderma, that is why Bob said studies of a 1,000 women cannot be accurate because the chances of having those diseases develop in those thousand women are small any way. It is not a large percentage. Connective tissue diseases are very new diseases, they are not diseases that have been around that we know about. There are not a lot of people that have them to study them. It is just a very rare disease. Which, of course, leads in my mind that everybody that has them out there that has called in and told me they have autoimmune diseases. These are very rare diseases. These are not diseases that you know occur.

WOMAN: My Mother is going to Dr. Weaver right now and he is trying to decide if she has one of these diseases. Every time he takes a blood sample to check her ANA he sends it to a different place and it comes back from the far end of the spectrum difference in the results. Did it locally, sent it to Mayo Clinic, and they are coming back with different ends of the spectrum results. He cannot diagnose it at this time.

PAULETTE: So you can understand why it is very hard.

WOMAN: Yes.

PAULETTE: It's very hard to predict whether or not you have this disease for one thing. The second thing is it connected to the breast implant. All of our research shows no. As Bob stated, it doesn't mean that it isn't but we certainly don't find any correlation at this time. In the 30 years of research that we have, it does not show that and we will continue to study this in the future. And certainly, women will ask you that. How do you know it doesn't? Well how come all of us out here are having these problems? You know, I can't answer that, I can tell you that we will continue to study in the future, I can tell you that we have a large epidemiological study going on at the University of Michigan. There is another study going on at New York University. There is just not enough known about the diseases or their correlation with implants to say for sure. We don't have enough evidence to say that it causes it. We don't have enough evidence to say it doesn't cause it. Again, I would caution you on the human adjutant disease, as you can see, the symptoms for H.A.D. reportedly include inflammation and irritation at the implant site, fluid accumulation, rash, general tiredness, weight loss, fever, skin sores, joint pain and hair loss. All things that could be attributed to other diseases.

WOMAN: To stress. Just normal stress.

PAULETTE: I think that some of things that we deal with here, like I said, I wake up in the morning with my joints sore and sometimes I don't know my name until I have a cup of coffee. I just feel like, what is happening out there with many women, and certainly there are women that are sick and I don't want to mislead you to say there are not. But I think that some of these women are just feeling those kind of aches and pains that all of us feel in our every day life and need something to pin it on and this is what it has become. Because if all of the research, scientific data is correct, then these are rare diseases. These are not diseases that occur in the numbers that we are seeing complaint. That is why Dow Corning keeps talking about sticking with scientific data rather than anodotal reports.

Another thing, that just popped into my head and I don't want to miss anything, when I have someone call me and we talk about autoimmune diseases and I talk to her about things that are in pamphlet I say "in the booklet I will be sending you at the end of every section there are references, if you would like to learn more about these diseases, you can go to your local library, you could go to the medical library at the hospital, you could ask your doctor if you could obtain copies of these articles, and read more about these diseases, become more informed."

Tumorgensis. Twenty eight years of clinical use indicates that silicone mammary prosthesis are not tumorigenic. Ordinary breast cancer in women with implants is what would be expected on statistical ground alone. There is a 20 year study that is being conducted right now in California by a Dr. Definin and Dr. Brody and Dr. Brody is a past president of the American Society of Plastic and Reconstructive Surgeons which is a Society that Board Certifies Plastic Surgeons. This study is 10.6 years into its use. What they have found is, and they are by way studying all types of cancer not just breast cancer but all types of cancer, the women that are included in this study have been implanted for 5 to 25 years. What they have found is that the incidences of cancer in women over the age 40 is what would be expected in the normal population. And,

the incidence of cancer in women under 40 in this study is less than what would be in the normal population. The reason for that may be, and I don't know the exact reason but what we can assume, is that the women under 40 who have had implants and are of this group are keeping a closer watch on their breasts than the normal population is doing and that may be why.
Certainly in this pamphlet when we talk about breast cancer, we talk about sarcomas occurring. Sarcomas as Bob told you the other day also, are common in laboratory rats. That is something that you can expect in all laboratory rats, do develop sarcomas and several sarcomas usually by the time that they die. Sarcomas are very rare in humans. The incidences of sarcoma is rare they do not usually occur.

From 1973 to 1986, they did a study, I mean reports, I mean medical journals go to studies all time and people report things all the time. In those 13 years for the whole country, the whole United States, there 445 cases reported of sarcomas occurring in women. Of those 445 cases, none of those women had implants. However, we certainly would expect that sooner or later, there will be a case of sarcoma with a woman with implants, simply because of the statistics. Sooner or later it is going to get to some one. But in 13 years there were 445 cases so you can understand that sarcoma is very rare. I think Bob talked to you in great detail yesterday about cancer. Cancer is something we feel very confident about, have done many, many tests, we have no evidence at all that says silicone breast implants cause cancer.

I think may be the conclusion here is probably the best thing to go over. The animal studies have raised only the issue of an association between silicone gel and sarcoma in laboratory rats. To date, studies have found no association between sarcomas and women with implants and increasing one cancer type in animals caused by a chemical or material, does not necessarily mean that other types of cancer will be caused by the same chemical or material in humans.

In that regard, the FDA and the National Institute of Health medical experts have concluded the results of the laboratory rat study is unlikely to apply to humans. Although a risk from silicone breast implants cannot be completely ruled out, there are at present no convincing animal or human studies that point to such a risk. If a cancer risk did exist from silicone breast implants it would be very small. Researchers in positions are continuing to study implants and remain responsive to the concerns of women who have or who are considering breast implants. Additional animal studies are being conducted to advance the understanding of how silicone breast implants interact with the body.

On the background information, in the packet also, there in the last paragraph on page 3, this is the FDA, also I want you to know speaking, the FDA put this out:

> As to the possibility of effects on other parts of the body related to the fetus for example or to autoimmune disease or cancer, at this point, these are only hypothetical questions. In weighing the possible long term risks of silicone breast implants it is important to bear in mind, and this applies to any number of substances we encounter in everyday life, that not being able to completely rule out a risk does not necessarily mean there is one.

Again, if you read these things, I have a lot of this highlighted in my book.

Want to take a break. I'll get you out of here at noon today.

AUDIENCE: Okay. Maybe a little earlier.

PAULETTE: One of the questions that have come most often is, is there a blood test to tell if I have silicone in my body? Is there a blood test to tell if I have silicone floating around? A couple of things I want to say on the subject of silicone floating around in your blood, is that to take blood from the body you use a syringe and a needle. The needle is covered with silicone and the syringe has silicone in it, then you put it in a test tube and that is coated with silicone.

WOMAN: Elden mentioned that.

PAULETTE: To say that there is a blood test, that is out. There is silicone in your body. There is not a blood test available that shows silicone. There is one, however, that shows silican, silican is a natural substance, silicone is a man made substance and natural silican appears in many forms, in green plants, many, many forms ... I want to show you, I am not a chemistry teacher, but I just want to show you how simple they are and what the difference is, we add carbon and hydrogen to silicone ..... this is silican, this is the natural substance, this is what's out there in nature ...

WOMAN: That is basically sand? Right.

PAULETTE: ... and this is man made substance where we have replaced oxygens with carbon and hydrogens. When you are dealing with someone about a blood test is that there are different levels to talk to some one about them. You are going to get someone who does not have a high degree of education on the other hand you are going to get someone who has a very high degree of education and understanding. You are going to have to deal with how far you take them through this explanation. You have to be very careful because you are going to be talking silican and silicone, you have to make sure that you differentiate in your putting the right name in the right place. There is no blood test, there is silicone in the body. Okay. I think as you are talking to this women these are the kinds of things you would say, "first, I think you need to understand that there is a difference between silican and silicone. Silican is found in nature. It is in most green plants, it is also found in drinking water. The reason for this is that silican makes up 28% of the earths' crust. There are assays for examination which show the level of silican in the blood. Silican is naturally in the blood. If you have a urine test, silican will show up. This silican then is in this urine test will fluctuate according to what you eat and drink. For example, if you had this urine test and the silican presence was determined, to what degree it was present is determined. If you drank a beer and you waited and hour and you had another urine test, the silican would be greatly elevated because there is silican in the hops in that beer. Silican is water soluble in a natural element. Silicone is man made and is not water soluble. So although examinations exist that trace silican in the blood, it has nothing to do with silicone. And I think you have to determine how far in that you can take her. If you can tell her no there is not a test, what test is out there is a test for silican which is a natural substance and not silicone which is a man made substance and that may be as far as you have to take her. You may have to take her a few steps further. It is going to depend on what she is asking you, what she is understanding. Again, we do not want to mislead people, we don't want to give them

inaccurate information, but we don't want to confuse them either. We don't want her coming off that phone more confused than she was when she came on it. And for some people the answer may be as simple as no there is not a test to tell if there is silicone in your blood.

These are just notes I took, I'm just checking to see if there is something I should be telling you that I'm not.

Do you have any questions about these complications we talked about?

WOMAN: Are we going to be getting any more information on this?

PAULETTE: Handouts, write ups. We certainly can give you the write up about the gel bleed and that kind of thing. But actually not much more.

WOMAN: So other than what's in the information packet, we need to kind of study and highlight.

PAULETTE: And certainly keep asking questions and keep taking notes. But I will guarantee that it won't be but 2 or 3 weeks and you will be into this so much that .... of course, there are going to be things that come up that you haven't heard before, and once you find out about it, once you go you know this, once you go do that investigation, you find an answer, you are always going to know that answer.

I would encourage you to share it around, why should everybody have to go research it.

WOMAN: Is that what you do at the 1:30 meeting?

PAULETTE: Yes. Also, if you have a question that is unusual to you or something, you may want to check with Wendy and Dawn, they have been at this several months and they may have the answer. Dawn is right now trying to put together some of the different names that we have heard implants called, not necessarily our implants but other implants. And so to kind of help you to discern whose implants they are talking about.

I guess we'll do the package insert. In our packet of information that we send out there are two package inserts that go out. The gel saline, Celastic MSI, gel saline, mammary implant HP, HP by the way stands for High Performance, in Celastic MSI mammary implant HPI gel fill. Again, all of the complications that we talked about earlier are contained in this package insert, under adverse reactions and complications and they do get into more detail than we talked about. If the patient ... as it well states on the packet, what is in the packet, if it is overview, if you would like more detailed information to consult the package insert. Understand that it is technical you may need a doctor to help you, understand that. It talks about precautions, what kinds of precautions should be used, things like pre-existing infections should be treated and resolved before implantation of the implant. It is recommended that before implantation, the prosthesis be carefully examined to assure product integrity, cleanliness. There are certain things that should be done before. It talks in number 6, about the steriles, Dow Corning does not endorse or recommend the introduction of drugs around the implant. The action of drugs

such as vitamins, anti-inflammatory steroids and antibiotics in conjunction with the breast implant has not been adequately tested by the manufacturer. The risks of such usage are unknown.

Number 11 implant life expectancy. It is not possible to predict the life expectancy of an implanted mammary prosthesis. Performance of the implanted prosthesis is not related solely to the design materials of composition or fabrication of the prosthesis. It also relates to the surgical procedures and its possible attendant medical complications and consequences and to the specific medical condition, psyological, anatomical and biological and behavioral aspects of the patient. Patients specifics how tall are you, what do you weigh, what do you do for a living, what do you do for recreation. All of these things affect the life of an implant. Most patients have had implants with no revisions. Others have required multiple revisions.

It also calls to you attention in the package insert, the gel saline on page 5, in bold print under adverse reactions and complications. It is the responsibility of the surgeon to provide the patient with this information prior to surgery. Dow Corning cannot sit in the surgeons office per se. Here comes one doc.

On the back of the package inserts it talks about warranty, Dow Corning warrants the reasonable care in selection of materials and methods of manufacture when used in application of this product. Dow Corning Wright shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this product. The foregoing warranties are as conditioned and limited and in lieu of and exclude all other warranties not expressly set forth herein whether expressed or implied by operation of law or otherwise. Dow Corning neither assumes nor authorizes any other person to assume for it any other or additional liabilities, or responsibility in connection with this product. Dow Corning Wright intends that this mammary implant product should be used only by physicians having received appropriate training in plastic surgery techniques.

If you would get someone on the telephone that wants to know about the warranty on your product, that is a customer relations questions. You do not answer questions on the warranties. They will be referred to the 800 number on your resource list for customer relations and, of course, that will be Lynn DeBolt, Shelley Blair, Rosalyn Wakefield, those names are on your resource list. If you get someone on the phone who says I have heard about your removal program and I am interested in seeking further information on that, transfer them next door and I will try to get someone in here this afternoon to talk to you about how to transfer, Donna and Jeff Rice, hopefully.

If you get someone on the phone who says your $1200 removal program is a joke, my surgery is going to run thousands and thousands of dollars. I have already talked to the doctor and he is looking at $10,000 and just who is going to pay for my babysitter while I'm doing this, and I'm losing time from work, and this is all your products fault and somebody is going to pay for this, somebody is going to take care of it. That is a Customer Relations call.

Now when you get someone like that on the telephone that you have to refer to Customer Relations, either through a warranty or through a threatening exchange between you two that

somebody is going to pay for all the problems that she has had. Something that is not removal, removal is quick and simple. I have heard about your removal program for $1200 and that is what I want to know about. Okay. Removal, by the way, Customer Relations will send them back to us, because of what I am just about to tell you. Before you give them the 800 number for Customer Relations to reimburse them for all of their problems, they will need to get their catalog and lot number for you. We have many many calls in Memphis and we cannot tie up telephone lines down there with people that don't belong to us that have a Surgitec implant that have a McGan implant. We do not want to bottleneck them down there for two reasons, we have enough of our own to handle for another they may not got a call back for two or three weeks and if it turns out that they had a McGan or Surgitec product here they set for three weeks in Memphis when they could have been negotiating with Surgitec or Mentor or McGan or any of the others out there, that's not fair to them either. So what we want them to do is to get their catalog and lot number and give us a call back and when you have that information....

AUDIENCE: Where do they get that from?

PAULETTE: I am going to tell you. When they get that information, when you have this information give me a call back and I will get you to some one who can help you with that. How you can find out what your catalog and lot number is, you can go to the physician who originally did the surgery. You can go to the facility where you had the surgery done. And I want you to make no mistake about the fact that everybody thinks they have a Dow Corning implant. Our name is what has been out there. Okay.

WOMAN: We only have what like 16% of the market share?

PAULETTE: 15% of the market share.

WOMAN: Does anyone else have a place they can call.

PAULETTE: Oh, yes. So what you need to do, this is what I would tell them, "What I can do is send you a packet of information. I also have a list of phone numbers that you may find very helpful, on this list are the other manufacturers numbers. I would like you to go to the doctor or go to the facility where you had this done and get me a catalog number and a lot number, if it is a Dow Corning Implant it will have a catalog and lot number, because that is what we use to identify our implants. That will tell me, specifically, what implant you have. If it turns out that you have another manufacturers number well I have already sent you this packet with their number included, you will have it on hand, you will be able to call them right away."

I will tell you undoubtedly that there are women who are going to say "I know I have the Dow Corning, my surgeon never used anything but Dow Corning". And sometimes they'll call you back and say or guess what the surgeon told me, very common for that to happen. Sometimes they won't ever call you back because they already have their numbers and they are on to someone else. You may want to explain to them at some point in this conversation that all manufacturers have someway to identify their implant. What Dow Corning uses is a catalog and lot number system, that catalog and lot number appears on a small sticker which is inside the

sterile container of the implant in the surgical arena when that implant is being placed all they have to do is peel that sticker and put it on to their medical records. So if the facility, the hospital or the doctor has that. Okay. If they call you back and they say, here's my lot number and here's my catalog number and this is a Dow Corning implant, you are going to know, most of our lot numbers start with HH, almost all of them. Some HM. And, the catalog numbers are usually three digits, may be a PO in the beginning and may be PO 528-0220 (the 220 is the ccs), may be 0330 (330 ccs), the last few numbers are the ccs. Okay. You may only ever get those three numbers 528, you may never get PO of whatever. Once you know whose implants they have and that they are Dow Corning and someone is paying for all of this stuff, then what you need to say is I need to get you to Customer Relations and I have an 800 number for you to call and you need to ask for Shelly Blair, Rosalyn Wakefield, Lynn Debolt, these are on the list. Lynns' name should be given last, she is going to law school, she is only in the office part time, 2 1/2 hours a day. She gets in she has 27 BMXs, as if she could even return 27 calls in 2 1/2 hours, right. So you need to give them in that order. As a matter of fact, Rosalyn could even be first, she is the newest in the paralegal family. So she has less case loads than any one else so give them to her first. I will tell you that Shelly is going through a real rough time as well .....

IMPLANT HOTLINE PROGRAM
TRAINING SESSION
MARCH 25, 26, 27, 1992

TAPE 5 SIDE B

[No sound..]

WOMEN: I think it depends on the person. Are these gals doing claims as well as questions and all that?

PAULETTE: Just claims.

WOMAN: But they would be there for our resource.

PAULETTE: That's right. Yes, if you have questions. Although, if you have questions about implants I could probably answer them as well as [undiscernible] either one.

WOMAN: So the reason we are sending them down to Customer Relations, if they are hostile, if someone is going to pay...

PAULETTE: The reason we are sending them to Customer Relations actually is that if we deal with them as a claim and we can satisfy all parties, then we avoid litigation.

WOMAN: But warranty questions go down there?

PAULETTE: Because if we have prep warranty, what is called a prep warranty and I can give you a little bit on information on that, but you don't really need to know to much because you are not going to deal with warranties. But we want you to know that if you have someone like this, I will try to keep you informed myself, Chris Meeder and Brigit Snow are also trained to do claims, and we will all be doing claims from out here. But if you get someone on the phone that is just so hostile and you can't do anything with them, some one is going to pay me -- they are going to do that right now and that's is all there is to it and I'm talking to somebody, don't you pass me on to someone else, and you know don't you be shoving me off to someone else.

WOMAN: Chris is helping us out with this too.

PAULETTE: Right. She is working 20 hours a week altogether. She is only doing claims. She doesn't do removal, she doesn't answer questions, she only does claims.

WOMAN: [undiscernible]. This is like dejavu. I worked for Brigit and Chris when I was in Litigations.

PAULETTE: And now it is coming back.

WOMAN: Can't get away.

PAULETTE: Comes back to haunt you doesn't it. So, if you get someone like that, one of us will try to handle that certainly. But understand that we also have other obligations here and there is no way we are going to be able to handle all the claims that come out of this Center or and that come out of Removal too. There just isn't any way, certainly we all have been trained to do it and we are all Paralegals. We need to do something to lighten the load in the office definitely. And, who knows, may if we got [undiscernible] would lighten it completely.

WOMAN: They will just move them up to Litigation.

PAULETTE: Yes, they'll just move them all over here.

WOMAN: Yes, they can't do the claims process so they'll send them over to Litigation.

PAULETTE: The Prep Warranty is a warranty that covers any interruption in the integrity of the shell of an implant within five years of implantation. For women who have no insurance, it will cover $600 -- it will pay them $600. And the cost of their implant. It used to be that we would replace the implant, but we don't make them anymore, so we can't replace them. $600, well I might as well go right into that too. We give them the cost of what their original implant was. If it was our implant, we will give you "X" amount of dollars for it, that's what you paid for that implant to begin with. We are not playing the game of other manufacturers. They are tripling and doubling the price of their saline implants, we can't play that game. We also, for litigation purposes, cannot say "here take this $900 and go buy a McGan Saline Implant", because if that McGan Saline Implant has a problem, they are going to come back and say Dow Corning told me to go get a McGan implant, I'm suing you. Why did you send me after a faulty implant? So what we will do is give them the money (or the cost of their original implant) along with the $600. The $600 is not to cover surgery fees. Most surgeons will redo this surgery under these conditions that fall under Prep Warranty. The anesthesia, hospital, any of those things, but not surgery.

WOMAN: Did I hear you say we would give them $600 to cover the cost of the original implant plus $600?

PAULETTE: Whatever the original implant cost, and they vary in cost some are $690, some are $490.

WOMAN: So this $600 is the same?

PAULETTE: In addition to, the $600.

WOMAN: So they are getting a total of $1,200.

PAULETTE: Not necessarily. If the original implant was $600, yes they would. But we have some implants that are out there that if she only had one are $400 and that if it was a pair that is $800. So it just depends on that. But you don't need to know a lot about the Prep but just what you understand what they are talking about when they call because we are not dealing with warranties at all. If somebody says they want to discuss the warranty, you don't know anything

about the warranty, you need to be dealing with Customer Relations.

Let me look at my little list here, let me see what else.

If you have somebody that wants to return an implant, we have [name] containers in the plant and along with that container, if this is a patient and they say I want to send it back to you for analysis, first thing to say to them -- are those implants sterile? have they been sterilized? If they say no I have them in my lingerie draw or my fridge, then the first thing you need to say to them is that they need to take those implants, put them in a Ziplock Bag, spray them like crazy with Lysol and take them back to their doctor because they have to be autoclaved and sterilized to be return. U. S. Postal Regulations will not let you return non-sterile explanted material through the mail.

WOMAN: How are they going to know?

PAULETTE: They are probably not. But we are not certainly going to promote them sending us non-sterile material through the mail. So if they say I cannot go back to my doctor that jerk, I am never dealing with him again and there is just no other alternative, then you tell them to spray the outside of that bag like crazy and wrap it up and put it in double Ziplock Bag and send it back to us.

WOMAN: Are they to label it any special way.

PAULETTE: By putting their name on it. Not inside the bag, but inside the box, so we will know.

WOMEN: Is the outside of the box to be labeled any special way?

PAULETTE: No.

WOMEN: We go by the weight? Containers?

PAULETTE: The [name] containers. If they take them back to their doctor to have them sterilized, we will be happy to send [name] containers to the doctor to return them to us in. We will also send him instructions on how to autoclave them. We have all of those things.

WOMAN: That is in the explant information.

PAULETTE: Yes. But we have gotten implants back in the Center -- very seldom, very seldom -- as I told you, I don't want you opening any boxes or anything in there, is because Brigit and I and Chris are doing claims in there, chances are we will be getting implants back. We will be getting implants back in all kinds of shapes and forms and containers, and we certainly don't want you opening anything....There are hepatitis shots available if you want them. We do a series of three shots. We do do that. I have offered them to everyone in the Implant Center. If you would like them you can have them. I personally don't want them.

WOMAN: Are the extremely painful or what?

PAULETTE: Hepatitis is not an airborne disease, so if you don't open it to handle it, you are probably safe. But if you feel safer having them, then have them.

WOMEN: I don't plan on opening any boxes. I'm not fondling any implants.

PAULETTE: Put one on my desk and I might. I'll try to give Tom a call and have him talk to you people. So understand, there are avenues if they want to replace them they can. When they return them, if somebody returns them and you get a box back and they have sent it to you, you say hey Vickie here is my implants, I'll send them to you. Then there's a way to get that implant over to Hemlock and there is a form. I'm not going to go over this in great detail I just want you to know that there is a form, and we have books and catalogs to do that, if that should happen to you and that has only happened one time since July in the Implant Center. Then we will deal with filling out the form at that time and getting it over there.

WOMAN: And Hemlock is taking these for non-destructive testing?

PAULETTE: And destructive testing -- it depends on what we are going to be allowed to do. That is another point that I'll be getting into. If they say I am sending this to you for analysis, then you tell them that these implants could be destroyed during analysis. If they say "no I don't want them to be destroyed" then you need to make sure that Hemlock knows this is non-destructive testing. If they want a copy of the analysis report, you must also inform Hemlock that they want a copy of the analysis report. What will happen is that report will come to you and you will send it to the patient and the caller.

Okay, next here is another test. Sometimes women call and they say I want my breast milk tested for silicone. We do not do that here. It takes gas liquid for chromatography to do that. There are some laboratories that will do that and there is a list of them that will do that. This is a very expensive test and we will not pay to have it done. Our research does not show that there is silicone in breast milk.

WOMEN: So all we do is give them a list of facilities.

PAULETTE: We send them the list of laboratories. If they would like it now, then give them the phone numbers. I don't know if that is in the updated list or not or in the resource list or not. But, we will make sure you get those, they are on the computer.

Another thing we need to talk about is the fact that.....Dow Corning in July released 10,000 pages of what was always considered proprietary information on breast implants. That is still available to the public and once in a while you'll still get a call for that. This is the form that we use for that. We do not handle this, Martha Biggs does this. If you get a request for this, what you need to do is take their name, their address and their telephone number and pass it to Martha. Martha sends them this order sheet and they can request certain pages, they can request the whole thing, they can do whatever they want to do. You should probably tell them to understand that we pay for shipping and mailing of this 10,000 pages -- but we do not pay for

copying, it is a nickel a page. They should understand up front that there is a charge for this.

WOMAN: How much is it a page?

PAULETTE: It is a nickel a page.

WOMAN: And what is the question, they'll ask.

PAULETTE: They'll say you released 10,000 pages of information and I want to have a copy of that.

WOMAN: That is because we said it is available to the public.

PAULETTE: This is not the 800 pages, that is coming up next. This is 10,000 pages. This was part of the PMA. This was clinicals that were in the PMA. In just this one, there are 9,728 pages for copying charges, $486.40.

WOMAN: If they want them all. How much is it for one?

PAULETTE: $486.40 -- if they want them all. You just tell them it is 5 cents a page, and there are 10,000 pages. They'll realize it is about 500 bucks to get this thing. Just as a side note, they released that one day, late in the day one day. At 6:00 in the morning, the President of McGan on the phone with Bob Reilly being the very first person to request these 10,000 pages of what was proprietary information. Interesting little note.

Now we come to Ann's favorite thing, the 800 pages of the 91 documents that Dow Corning recently released. There were memos in there and there were also studies. That is also handled through Martha Biggs. There is no charge for this.

WOMAN: Isn't that a hefty shipping charge?

PAULETTE: Hefty copying charge. There is no charge for that whatsoever. If they want that you take their name, their address and phone number and process it to Martha. This person wants the 800 pages and that is how they refer to that also, they want the 800 pages. The memos you just released.

WOMAN: The ridiculous part is, if they knew what they were asking for, half of these things are not even legible because they are old file records, they're old memos, the print is faded, some of them are so in copying over the years, it looks like a black border. I had a really devil of a time getting a legible copy for our attorneys to read. I mean, and this is the original. This is crazy.

PAULETTE: And, besides the memos and all of that, the clinical studies in this, as well as that, this is clinical studies. This is not something that lay person is going to understand in any way shape or form. Knowing what I know, I didn't know what? I had no idea. But it is out there and it is available.

WOMAN: There is no freight charge on either of those but there is a cost per page for the first one?

PAULETTE: For the 10,000 page.

WOMAN: The other one is absolutely free

PAULETTE: Right.

WOMAN: Send to Martha Biggs.

PAULETTE: One more thing and we'll go to lunch. It is lunch time already.

When you are on the phone, you are not allowed to share personal experiences. That is a no, no. However, you realize that there are going to be times when that cannot be avoided -- when that woman says to you "have you ever had surgery?" -- what are you going to say? If you have had surgery then the answer to that is yes. But that is me and what I am interested in is you. Let's talk about you, just as quickly as you possibly can turn it right back to them. If you had cancer would you have implants? Yes I would, but that is my concern. Let's talk about your concerns. I think that is one thing the FDA wanted, they did not want us to share personal experiences which I can understand, however, I don't think you are always going to be able to avoid it. If she asks you a direct question, "have you ever had surgery?", you know you are going to have to answer that -- I mean you can't be rude. You are going to have to say "yes I have" or "no I haven't", as the case may be. But you can share personal experiences, but just as quickly as possible, turn it back to her. She is our concern. She is who we are worried about. Let's talk about you.

The other thing just while it is in my head, then I promise I'll let you go. Is that you are going to find women on the phone who, when you send them to find out what their catalog and lot number is, now I have to make another phone call, I have to be inconvenienced to do this or do that. Geez, aren't you going to help me -- the answer to that question and the best response that I have found is that "let's work together on this to get this problem solved for you". My job is going to be to send you this packet of information, send you this list of other manufacturers numbers and your job is going to be to find out whose implants you have. You call me back and we'll work from there on it together. But we will together get to the bottom of what your problems are. If we do this as a team, it works much better. They accept it a whole lot better, a whole lot better. Which must be the psychology in hospitals of "how are we doing tonight? We got some medicine to take", "no, I have some medicine to take".

WOMAN: Do you have a mouse in your pocket or what?

PAULETTE: Yes. Really.

WOMAN: Usually what they are asking, is what you need them to do.

PAULETTE: I think we are up to typical questions and answers.

WOMAN: Will we be doing that before lunch?

PAULETTE: The lines you that you will be working with over at the Implant Information Center are established in a hunt group, what that means is that when a call comes in on either of the 800 lines here and here they will jump on to that hunt group. When the first line is busy, the second call coming in will go to the second number, here the 8688 line. When the first two are busy, the next call will go to 8708, etc., on through that hunt group. That happens in just a split second, what happens when a call comes in to the first one, if it is busied out it will just look for the next available one that quick and it will find the available operator to put a call on that line. One of the reasons that it is very critical for all of this to work the way that it is designed to work, one thing you need to do to make that work, if you are leaving your work station, just take the phone off the hook, that way that will appear as a busy station and it will by pass it to the next available.

WOMAN: Does it beep.

PAULETTE: Yes it does, but you all have headsets, and that is optional, if you prefer not to use the headset you do not have to but for those of you who are choosing to use the headsets what you can do is put it in the headset mode and then dial the volume down and then you won't hear that. Because you will get the message if you are trying to place a call, please dial again, and then the loud beeping sound to tell you that you are off the hook. So you can eliminate that by putting it in the headset mode, you have it on here and then putting the volume to one, you are not going to hear it. So you do have to go off hook to busy out your station, if you are not going to be there. What will happen if you don't do that, your phone will ring three times on the 8-- whatever, whatever number and, if it is not answered by the third call, it will go into a BMX Mail Box, it will not forward on through the hunt group so that's why it is critical that you take your phone off the hook, if you leave your work station.

If you are going to be at your work station, there is another way to by pass your phone, and that is to go in on your first line, which is your 8, 708 or whatever your phone number is and do a hard forward and I think some of you are familiar with dialing 118 and the four digit number and if you are on, let's say your on 8832 and you want to leave your work station for an extended period of time you can hard forward by dialing 118, 8833 or the next available operator and all your calls then will by pass this phone. Another time you are going to want to do that is if you are on your second line, you cannot get the other one because you are unable to put your call on hold, that's another time you are going to want to hard forward so that you will only hear, you'll just hear part of a ring going, just to let you know that that line is call forwarded and your calls are going to go to the next available number.

WOMAN: Okay. So we will have a second line that's like our personal phone number where family and friends can call in.

PAULETTE: That's right.

WOMAN: Okay, so when we are on that phone, if we haven't done the call forwarding then it will be sent to BMX on the first line?