Letter from Dr Johnson in regard to String Implants dated February 2001

Klaus,

I have personally placed a moratorium on augmenting, re-augmenting, or replacing existing implants with the PPP string until a reliable major breast implant manufacturer is willing to commit to working with me on the continued development, production, and eventual FDA approval of the implant. Just for your information I will enclose some additional information on the PPP Implant.

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I hesitate to call this alternate material a "New" implant, because in the world of surgery it has been used with absolute success in the human body for over 35 years. It just never has been reported in the medical literature to have been used as a material to augment the female breast. If you are genuinely interested in informing yourself on this material, new to the world of breast implants, please click on the following link (Bard Mesh is pure polypropylene- PPP. I have 2 pieces of this Marlex mesh in my body used to repair inguinal hernias) http://www.davol.com/mesh.htm
Once you click on this link and read it I think you will see why I picked PPP as the most ideal product to start out with a totally new, totally non-silicone, breast implant. It is perhaps the least reactive of all foreign implant materials presently in use, save perhaps stainless steel, and stainless steel wouldn't make a very good breast implant.

I assume you have been to my web site and read the material I have published on the web about my use of the PPP as a breast implant. If you have not, then you need to take a few minutes and do so if you want to be informed on this subject. You can go directly to that info by clicking on this link >>>>> http://www.certified-plastic-surg.com/publicat1.htm <<<<< (read the info about the new implant, and click on the blue bar to read the International Publication about the new material). The info was placed on my web page in December 1998 (if you are genuinely interested in informing yourself on this material, new to the world of breast implants, you need to read this info). Since then we have continued to follow up on the patients and have now done over 50 patients with this new implant. No surgical procedure has yet been devised or performed by man that does not produce or result in some complications, and the same is true for the use of PPP to augment breasts. However, the complications that have occurred have not been of such severity or of such an unusual nature or predictability so as to discourage us from continuing our efforts to perfect a totally non-silicone implant to augment the female breast.

Permit me to use a simile to explain why we are not experimenting on the patients who have the PPP implants. Most savvy adults know about Botox, made from botulism toxin. The FDA approved it **only** to treat spasm of the muscles around the eyes, and the makers of Botox can only advertise it for that purpose. However doctors can buy the Botox and use it any way they choose. And, as you probably know, Botox is now being widely used for many other purposes including stopping and preventing wrinkles around the face. When doctors use Botox for any purpose other than spasm of the eye muscles, they are using the product "off label". Eventually, the makers of Botox will have enough data gathered on the off label use of Botox to go back and ask the FDA for their approval for the use of Botox in the many ways it is already being used. Did you know, for example, that liposuction has never been approved by the FDA, and no liposuction machines, accessories, cannulas, etc., are approved by the FDA for sale to do liposuction?

The same is true of polypropylene (PPP). It has been approved by the FDA for many different uses in the human body, but approval to use PPP as a breast implant has never been requested from the FDA. That is what

we are presently working toward, and as we do so, we are presently using PPP "off label" as a breast implant as we gather experience and data to take to the FDA. This is also why we presently require the patient receive so much information, including seeing a 3 hour video before we will consider her as a candidate for the PPP implant. We have a patent pending to cover all aspects, configurations, and possibilities of these implant ideas, and as soon as we can complete an agreement with a major company that has the technology and the foresight to help develop these ideas, we will file an application with the FDA to begin clinical trials which means we will be getting other cosmetic and plastic surgeons from around the country and the world to participate in the use and evaluation of these alternate implants.

1) We have not had any true spherical capsular contractures as would be seen with a silicone or saline implant. There are varying degrees of firmness just as in natural breasts, and the breasts can appear very firm if the patient doesn't form adequate serum in the breast pocket around the string. An eighteen year old girl who has just developed C or D cup size breasts will have very firm-solid breasts, but we call them normal. A thirty-five year old woman who has had a couple of kids and who has C or D cup size breasts will have very soft breasts, but we call them normal. As the new year 2000 rolled in we had over 50 patients in our series of alternate string implants. When the string implants are implanted, they are firm. At the time of surgery we inject saline into the pocket after we have the breast pockets closed "water tight". Of course, the saline absorbs, but with time the body replaces the saline with serum. The more serum your body puts into the pocket, the softer the breasts feel. We cannot control the body's development of and the input of the serum (fluid) into the pocket with the string. However if too much serum is formed, we can remove some with a syringe and needle. If not enough serum is formed, we can inject saline into the pocket.

2) The implants take the shape of their container, which is the breast-skin envelop of the patient, and in all patients (except one breast on one patient) they have at the worst been satisfactory in shape, and most have been adequate in feel. At the best they are so natural that most physicians could not tell the difference in the augmented breast and an unaugmented breast. As for anatomical (contoured) saline or silicone implants, I don't like them, they are unnecessary, and I don't use them. Contoured (textured) implants are not new. I first used them in 1972 (my plastic surgery Professor, Dr. Robert Wise, now deceased, first developed them). Back then we didn't have textured surface implants and Dr. Wise's implants would rotate and make the breast look deformed. Today's textured surface implants usually stick to the inside of the breast and don't rotate, HOWEVER, because of their very nature, textured implants must have a thicker shell and that makes them much more prone to produce wrinkles and because the textured surface is actually made by intentionally placing thousands of tiny defects in the outer shell during manufacture, textured implants have a higher leakage rate than do smooth surface silicone. I could use contoured implants with the Endoscopic procedure if a patient insisted, but I think you can see why I don't like them.

3) The procedure for augmentation with the string, though technically different, is similar to any other augmentation in that a pocket is created. I use a tissue expander/dissector to create the pocket, in a manner similar to the way we do the Endoscopic breast augmentation) because the tissue expander/dissector can be done with a very **small incision**, the chance of hematoma formation is **20 times less likely** than with other techniques, and the chance of **loss of nipple sensation is only about 1%** as compared to 15% to 30% with other techniques. I prefer to place the implant above the muscle--that's where NATURE put your breasts originally. Massage, in the same manner that you have to beat and bang on some silicone/saline augmented breasts, is not required. Some manipulation may be beneficial at times. I always place the string implants in the subglandular position, and would do subpectoral placement only in an unusual circumstance.

4) When they are normal, these string implants feel more like the real thing than I've ever seen in any other type breast implant (except fat), and I have done breast implants on approximately 10,000 patients since 1972, so I think I know what augmented and unaugmented breasts feel like.

Approximately 40 of the string implant patients originally had silicone or saline implants with complications,

mostly spherical contractures. After their saline/silicone implants were removed and the string implants were inserted, **EVERY PATIENT** stated that the string implants felt more like a part of them than any type implant they had ever had in place. We are now over 2 years post operative for the first series of string implant patients. We have selected the majority of our string implant patients from the patient groups who normally have a high rate of problems or complications, especially the group of women who are adult entertainers with extremely large breasts, and from patients who already have or had other types of implants and have had complications requiring one or more surgeries. I had an agreement with the patients that after 3 months I would replace their implants with saline implants upon their request, for what ever reason they had. I HAVE HAD ONLY 4 PATIENTS OUT OF 60 MAKE SUCH A REQUEST.

Those who were married or had "significant other" partners reported a high degree of acceptance and satisfaction by their partners. Our longest followup is 25 months and any woman who has had saline/silicone implants with complications knows that if she is going to have those aggressive, painful or deforming problems, she usually knows something is wrong by 1 year. I am fully aware that the implant problems can happen anytime between Day One and Day One Hundred and with the string implants we need to follow our patients "forever", to learn what may happen and figure out how to treat it and how to prevent it.

MENTOR IMPLANT COMPANY negotiated with us for 2 years about buying our patent on the string implant, and on June 14, 2000, they backed out because they were afraid they couldn't make enough money although they stated, "We are certain Dr. Johnson or someone will bring this implant to the market at some time in the future."

As of this date, June 14, 2000, I will not be accepting any new patients for the large string implants until I have had sufficient time to reevaluate and continue ongoing evaluations of all string patients, and make arrangements and agreements with another company, individual, or group of individuals who will work with me to get this approved by the FDA.

Update, January 01, 01: I will no longer accept any new patients for the PPP String implant augmentation , regardless of size, until I have accomplished what is described in the above paragraph. If you are interested in the use of saline implants plus correction of present deformities (if any) in your breasts, I will be happy to send you more information upon your request.

If and when the time comes that I am ready to accept new string patients, I will not accept everyone as a candidate for string implant surgery. Please contact me if you need additional info. It would be difficult to do a complete consultation over the phone or by e-mail. If you are really interested call 1-800-593-0011 or 713-960-9334 and make an appointment to come to our office and we will fully inform you on the topic of breast augmentation. Bring a copy of this communication with you and the consultation will be free. We accept credit cards and financing is available. We have an extensive **informed consent** procedure, so please ask my surgery coordinator, Robin, about it.

Sincerely,

Gerald W. Johnson, M.D.
Website Address: http://www.certified-plastic-surg.com