

18th April 2012

I have very broad shoulders with a naturally large behind and I had a flat chest, so I felt like I looked like a boy with a completely out of proportion body. I was very self conscious of my partner seeing my breasts and I found it came between us both physically and mentally.

After years of considering whether to get breast implants I finally decided to take the plunge at the beginning of 2008 after doing extensive research on the risk factors. I knew there was always a chance of rupture, especially after the 10 year mark, and that it would probably be best to replace them every ten or twelve years to be on the safe side. I was also under the understanding that due to the cohesive nature of the medical grade silicone it generally stayed in place and did not travel in your body even if it were to rupture, and if it did travel it was medical grade and therefore shouldn't cause tissue irritation. This would mean if one did rupture down the track I would need to have it replaced but it should not have any health consequences and therefore shouldn't be a matter of urgency. I did all the research before I made the decision to get breast implants and NOT ONCE did I ever consider a risk may be the implant would contain industrial grade silicone. This wasn't mentioned as a risk anywhere and certainly wasn't told to me by my surgeon. Due to the non-cohesive nature of this silicone there are many girls who have had to have their lymph nodes removed, some though multiple surgeries.

After seeing information about PIP's on the television on the 11th of March 2012 I called the agency I went through for my surgery to find out if I had these implants, never expecting that I actually would. When they confirmed I did have the PIP's I was devastated and became an emotional wreck! I vomited and cried on and off for a couple of days and I couldn't sleep, I was so distressed about what I had in my body. Knowing you most likely have industrial grade silicone in your body isn't the nicest feeling in the world. I have now known I have PIP's for five and a half weeks and it's been the most awful, distressing time in my life. My work has suffered, my studies have suffered, my partner has suffered, my family has suffered, my friends have suffered, and most of all I have suffered. I don't think I have had more than four hours sleep per night since I found out and can't think about anything else.

I promptly made an appointment with my doctor to obtain an ultrasound referral, and within a week of finding out I had the PIP's I was having an ultrasound being told there was a severe rupture in my left breast, and there was that silicone "absolutely everywhere" all around the breast. As my original surgeon retired I had to find a new surgeon to take the implants out.

Although he has reduced his fee for PIP cases his fee alone is still \$3,000 and the cheapest hospital fees I can get is \$1,500 and I have no health insurance. I have taken the option of just having a local anaesthetic as I can't afford to have a general. My credit card is now completely maxed out and I have had to borrow \$2,500 off my partner.

Over the last few years I have become more and more exhausted, my body aches, my hair falls out, I drink at least eight litres of water a day and am still incredibly dehydrated, and my eyes get a dry spot on them within one second when my optometrist considers a dry eye to get a dry spot within ten seconds. I have mentioned these problems to my doctors who have ran tests only to come back with no answers. After finding out about the PIP's I have done a lot of research online and come across hundreds of women who have the same or similar symptoms as me and all have PIP's. I don't believe this to be a coincidence.

My new surgeon has said that the PIP rupture rate of his clients is approximately 30%. I have also read plastic surgeons in the UK state one in three of their clients have ruptures. Yet I believe the TGA is stating a rupture rate of around 2.5 to 5%! I understand they don't have the ability to know exactly how many women have the PIP implants and how to contact them but I find the difference in figures to be extremely concerning. The TGA figures must be completely incorrect, and this is what they are using to advise consumers in regards to their health! I also find the fact that they are using Dr Fleming as one of their main advisors on the issue very concerning as he is apparently one of the largest PIP implanters, if not the largest, in the whole country. Do you not think that because of this he does not feel the need to "cover his own arse"? I wonder if he were to advise all of his patients to be tested for rupture what rate would come back? I would bet my life it would be much more than 5%.

We rely on the TGA to thoroughly and regularly test medical devices. Why were these implants only tested once? They tested the structure containing the silicone for its strength but did they ever test what was inside? They are now conducting more tests stating the strength of the shell complies with regulations and using this as the basis for why they are believed to be safe to be left in the body, and to justify how they made their mistake. What they don't seem to be testing for is the impact the industrial grade silicone contained inside the shell has on degrading the quality and strength of the shell. This is what seems to be the problem with the ruptures, not the initial strength of the shell, so to use that basis for testing seems completely ridiculous to me. And not only do they not seem to be testing how much the silicone inside degrades the quality of the shell, but adding to the fact they are in a warm

moist environment in the human body this degradation would have to be even more accelerated.

Why would authorities in the UK order them all to be removed if they didn't believe there to be serious health consequences? I for one am not comfortable with leaving an industrial grade silicone in my body for a minute longer than I have to. To me that is just common sense.

I think the way the TGA has handled this matter is appalling. I think they need to be basing the rupture rate on rates supplied by surgeons seeing these women, and not by waiting for the surgeons to contact them. I think the TGA should be contacting surgeons say once a month for updated figures and having this contact mandated. Not only will not all surgeons take the time to ensure they contact the TGA with all ruptures (as let's face it, they've never been this busy in their lives trying to fix this mess), but most women would not even know how to contact the TGA to report their ruptures or even think they should.

The TGA know they have a lot to answer for to let this product be used in Australia, and of course they will do whatever they can to try and avoid responsibility. The FDA did not allow this product to be used in the US. I have read a report from an inspection they did on of one of the PIP factories and it was extremely disturbing! It seems the TGA has seriously let us down and someone needs to take a look at their standards for approving these devices and the tests they use to try and find a way to stop something like this from ever happening again.

Thank you for your time.