The Making of an Implant

In the early 1900's a mixture of paraffin, petroleum jelly, and olive oil was used to enlarge the female breast. Japanese women first began using silicone injections in the 1940's. Los Vegas show girls began using silicone injections modified by adding cottonseed oil (to prevent scarring and oil migration). By the late 1960's the FDA had classified silicone injections as a drug and eventually banned them altogether. In response to the FDA's ban of silicone injections, implantable prosthesis consisting of a silicone bag containing silicone gel, saline, or other oils were manufactured and sold world wide. Although several styles with minor variations have been marketed in the last 20 years, today's mammary prosthesis is still essentially the same bag of jelly concept. Due to flaws in the manufacturing process though, many of the hazards that caused silicone injections to be banned in the 1960s' have reappeared. A brief look at this process reveals how.

The elastomer, or envelope containing the jel, saline or other filling substance is fabricated by immersing a mandrel of appropriate size into the companies's mixture of various silicone agents and chemical components that will eventually form the outer shell. Depending on the thickness desired, the mandrel can be immersed or redipped any number of times until the desired thickness is achieved. For example, Dow Corning implants are dipped a total of four times. After the last dip, the mandrels are inverted and allowed to dry. During the shell fabrication phase, tight quality control is essential. If the mandrel is immersed too

quickly, air entrapment may occur, especially at the top of the mandrel, weakening the shell. Similarly, if the chemicals composing the elastomer are outdated and not as strong as manufacturing specifications anticipate, or too strong, untoward results can occur. Improper mixture of components also yields unexpected and often undesirable results. Obviously, the purity of materials used to manufacture the implant is essential. The next step is to cure, or bake the shell. Baking times and temperatures vary from manufacturer to manufacturer. Dow's coated mandrels are cured 15 minutes at 70 degrees C. and then one hour at 200 degrees C. and allowed to cool. The cured, coated mandrel is then removed from the mandrel. As it is often necessary to cut a hole concentric to the hook-up appartus to remove the elastomer from the mold, extra care must be taken to insure that the cut is smooth to prevent nicks that could manifest after implantation. The maufacturer at this point should inspect the elastomer paying particular attention to the thickness of the shell just made. Unfortunately, this isn't always done. Implants with spots in the shell measuring as little as .001 of an inch are not unheard of. During direct examination in the case of Johnson v. MEC, Pierre Blais compared the thickness of an implant manufactured by MEC/Surgitek to that of a condom. Others have concluded that the shell is about the same as a piece of clear kitchen wrap. Four thickness readings are taken at MEC and then averaged. If the average is within the manufacturer's tolerances, it passes.

After the mold is stripped from the mandrel it is washed with an isopropyl alcohol solvent followed by evaporation to remove alcohol residues. The mammary shells are now ready for sealing. Sealing operation is accomplished to close the opening left by removal of the shell from the mold. Some manufacturers may refer to this as the stripping operation. This process involves fabrication of a patch from materials compatible with the shell following by heat sealing. The patch is then glued to the hole with a silicone based glue. The shell and patch are then heated so that the hole is patched much like a a bicycle inner tube is patched. If the patch material is slightly thicker that the rest of the implant, it has less elasticity and the result is a weak spot. Additionally, the stresses caused by repeated creasing are magnified because the patch would tend to pull away from the rest of the implant.

If a Dacron patch is going to be attached to the implant, it would typically occur at this point.

Gel is introduced by using a needle to poke a hold through the sealer patch. With both Surgitek and Dow implants, the amount of gel to be injected is determined by weight and controlled generally by an automatic dispensing system. If large bubbles appear in a Surgitek implant, they are aspirated using a needle. After injection, Surgitek implants are placed in a vacuum chamber to remove remaining air bubbles from the gel. Visual contaminants are removed using an air suction needle.

The opening remaining for both Dow and Surgitek implants following gel injection is sealed by application of a bonding solution (adhesive) to the needle hole. Finally, the implant is baked to cure the gel and establish a seal of the bonding solution to the implant.

The next step is a quality control check. The implant is weighed and visually inspected. Visual contaminant is removed. Surgitek implants are then inspected using a thin spot test and pressure tested.

Packaging of the device involves the placement of the device in an inner plastic bowl. A lid is then heat sealed over the top. The sealed inner bowl is then placed in an outer bowl and again sealed.

Sterilization is accomplished at Surgitek through the use of ethylene oxide. This is done by contract vendors.

If you have been reading publications such as this, press releases involving implant defects, or even casually listening to public radio, you are undoubtedly aware of ghastly allegations involving implant manufacturing flaws. Records gathered so far report instances of dirty and improperly manufactured gel, implants being made with outdated materials, discontinued products being dumped overseas and even company employees blowing into the implants to see if they are air tight. If the women that you represent was implanted with a bilumen type of implant,(an implant within an implant), there are records which suggest the inner lumen is sometimes a rejected outer shell. Each of these problems exists

as a result of flaws in the manufacturing system I have just described.

The process I have discussed reflects how an implant was made in the early 1990's. While the basic product idea has changed little since its introduction in the late 60's, the manufacturing process has. For example, Surgitek implants used to be sold to the physician clean but not sterile. Presumably, this means that bacteria could grow while the product sat on the doctors shelf. Bacterial growth could be significant because some implants sat on the shelf for as much as two years before being implanted. While sterilization would hopefully kill the bacteria, the dead bacterial particulate would still be present unless somehow removed by the doctor. More recently, Surgitek implants were sold after utilization of ETO sterilization.

Investigating the particular manufacturing process of your defendant can in part be solved by the manufacturer's own records. Implant makers are required to maintain tracing records so that every step in the manufacturing process is traceable. Documents from several different areas of the manufacturing chains including the raw materials, components, and the identification of the individuals the manufacturing process are available from the various manufacturers and in some case the MDL depository in Cincinnati, Ohio. I also recommend that you review the Premarket Approval Application submitted to the FDA to follow up on how a particular manufacturer maintains device history records.