LOTUS™
BREAST IMPLANT

Dr. Rehnke has told you about an alternative option to silicone breast implants - the LOTUS™ breast implant. This is an alternative approach to breast enhancement surgery developed by Dr. Rehnke, that makes use of a naturally occurring absorbable, polyester mesh scaffold, which is placed under the skin, after removal of the breast gland during a skin and nipple sparing mastectomy. Since a silicone implant cannot integrate with tissues, the body isolates it in a collagen scar tissue capsule. The characteristics of this capsule vary from very thin and elastic, to thick inelastic and tight - this can lead to breast reconstruction deformity. If the capsule is too elastic, the weight of the implant can stretch out the shape of the breast causing it to sag and loose its fullness; this is known as "bottoming out." On the other hand a thick tight capsule, known as "capsular contracture", can lead to a hard reconstructed breast that may have an un-natural, and asymmetric shape. Usually, reconstructed breasts with capsular contracture are un-naturally high and defy gravity. Unfortunately, in situations of bilateral reconstructions, the chances of having bottoming out on one side, and contracture on the other are all too common. On the other hand, the risk of infection or extrusion (a breaking down of the tissue covering an implant leading to its removal) is an uncommon problem of silicone implants, but does often occur. In thin patients with weak tissue the silicone implant can be visible through the skin. Finally, all implants eventually wear out and rupture, leading to their removal and possible replacement.

You may have personally experienced one, or all, of these complications. Or, you may have had previous breast implant reconstructive surgery, but don't like the idea of a permanent, foreign implant in your body. It might be that your skin, connective tissue, and body fat are too thin or weak for silicone; while on the other hand you may have tried again and again to have silicone implants placed only to experience repeated failure. Whichever the case, the LOTUS™ breast implant was invented as an alternative to saline or silicone breast implants.

Long term absorbable mesh material was first used in medicine in the early part of this decade and has been implanted in millions of patients worldwide. The FDA has approved its use as follows: "…….. indicated for use as a transitory scaffold for soft tissue support and repair to reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction." Our practice has used long term absorbable mesh since 2012, and began creating the

LOTUS™ breast implant in early 2015. In the first three and one-half years of use, we have implanted 38 LOTUS™ breast implants for reconstruction of women's breasts who have undergone mastectomies in the treatment of breast cancer. We have observed another 14 LOTUS™ breast implants placed for cosmetic purposes. The favorable outcomes, low complication rates, and experience with mammogram and MRI surveillance post op have led to our use of the LOTUS™ breast implant in selected cosmetic cases. Until hundreds and thousands of absorbable scaffolds are used over decades, our full knowledge of the usefulness and possible complications or risks of this new absorbable implant is unknown.

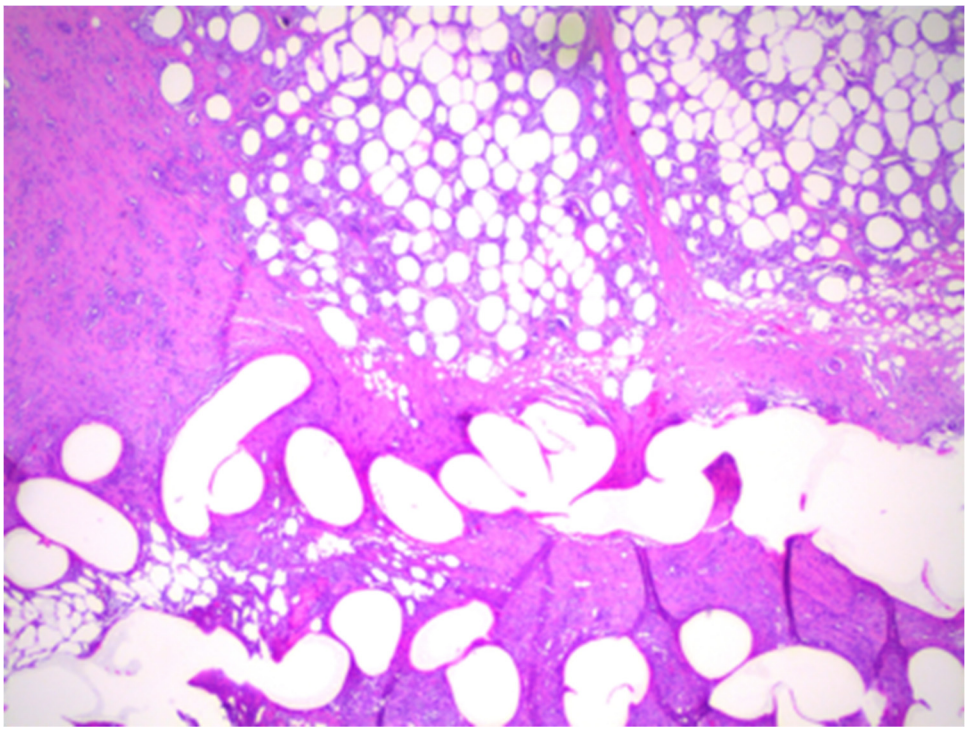
[To see one of these cases and watch a video of this cosmetic procedure, log on to YouTube: https://www.youtube.com/watch?v=JT2-zOvwFGU . ]

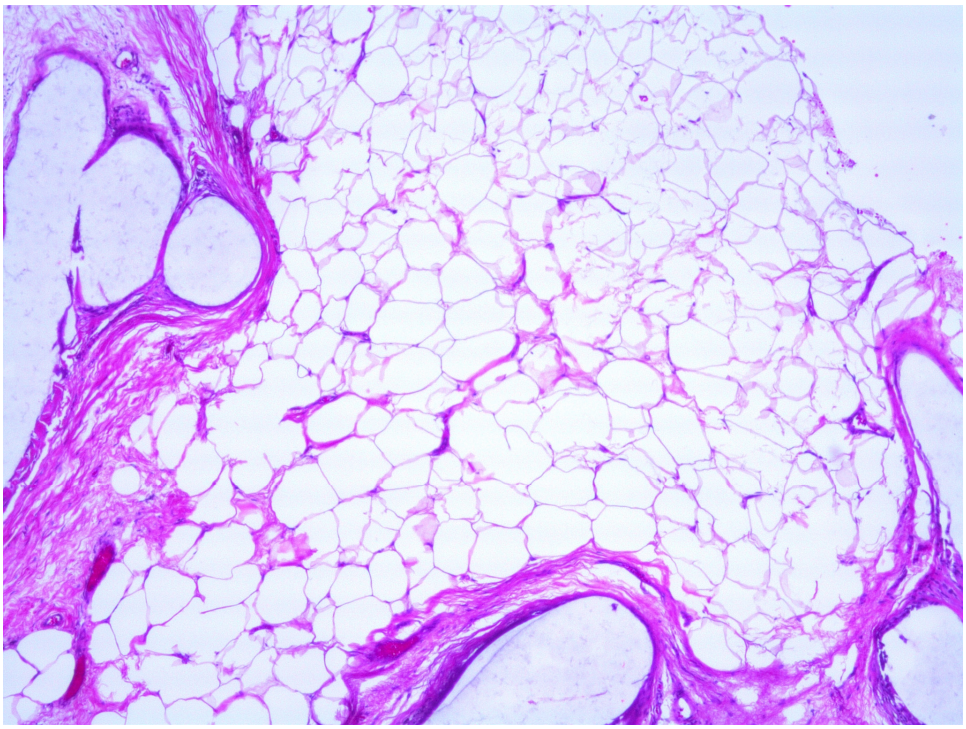
The LOTUS™ breast implant is constructed in the operating room on the sterile back table, prior to the patient entering the operating room. We construct each implant from two and one-half sheets of Galaflex, a sterile, knit monofilament fiber, made of poly 4 hydroxybuterate (P4HB).

To learn more go to the GalaFLEX web site at: https://www.galateasurgical.com/ and https://www.galateasurgical.com/surgical-scaffolds/what-is-galatea-scaffold/ .

P4HB is a naturally occurring polyester found in certain rare bacteria present in our GI tract. Tepha, the parent company and manufacturer of the P4HB mesh, holds the patent on the recombinant DNA technology which allows placing the gene for P4HB into a strain of E. coli. This common bacteria is used to produce the poly 4 hydroxybuterate in a fermentation process. The purified product is then extruded into a monofilament, similar to fishing line. The filament is then knit into a two-dimensional sheet of mesh material. We use sheets 6x8 inches in dimension, and fold and suture the cut pieces together in a technique similar to Origami. Multiple connections, created with suture knots, distribute the compression forces throughout the structure. The typical device measures 9 cm. in diameter and 5 cm. in projection - accounting for a volume of roughly 240 cc. Testing in the laboratory has shown it can be compressed by 80% its height multiple times and return to within 2 mm. of its original size. This design allows for a "bend but not break" structure. It contains about 24 small "cups" that divide the total volume into 10cc subunits.

The mesh structure acts as a scaffold or trellis for the ingrowth of patient cells and tissues. In our 42 cases of LOTUS™ breast implantation, lipo-aspirate was used to coat the surfaces of the scaffold. Microscopic analysis of these implants thirteen months post implantation (next page), showed integration of the scaffold into patient connective tissue and blood vessels, with healthy fat tissue within the layers of P4HB.





Ingrowth of patient connective tissue, capillaries, and grafted fat cells, one year post mastectomy and implantation of LOTUS™ implant.

The possible complications that could conceivably be associated with use of the LOTUS™ breast implant are similar to those found with silicone implants:

1. Infection - Any breakdown of the incision used to perform the surgery can open the door to bacteria making its way into the body. If the immune system and antibiotics cannot fight the infection off, the implant must be removed. Two of our reconstruction patients have had bacterial contamination of the healing wound after implantation. Both were able to overcome the infection and heal with the aid of oral antibiotics. The P4HB mesh is reported to have low infection rates. This has to do with its monofilament fiber composition and large pore size mesh design. The body's healing cells completely integrate the mesh making it similar to a well-vascularized tissue - instead of a foreign implant. Additionally, a study of the surrounding fluid taken from one of our patients' healing LOTUS™ breast implants one month and one-half post implantation, showed the presence of Anti-Microbial Proteins. These proteins produced by white blood cells kill all types of bacteria, fungus and viruses, and are part of the immune system's natural defense against infection. P4HB seems to naturally encourage this healthy immune response.
2. Exposure/Extrusion - If the tissue covering an implant is too weak and unhealthy, or if infection causes break down, the implant can become uncovered and exposed to the outside world. When this happens with silicone implants it almost universally means the implant must be removed. One would expect this complication to be higher in reconstruction patients who have had complete mastectomies. Our experience using the LOTUS™ breast implant in 38 mastectomy reconstructions over the last 3.5 years, has not seen any extrusions. We believe that, due to P4HB's biocompatibility and resistance to infection, extrusion will be a very rare event.
3. Visibility/Palpability - The scaffold can be visible in thin patients who undergo breast reconstruction following mastectomy. This is why serial fat grafting procedures are performed every few months following implantation, to cover and hide the dissolving implant with fat. It is possible to vaguely feel the LOTUS™ as a firm central structure similar to a young woman's natural breast gland.
4. Scar Contracture - We have not seen scar capsular contracture with the LOTUS™ breast implant. Unlike silicone implants, it is easy for the body to grow into the LOTUS™ breast implant and integrate with the surrounding connective tissue and fat. We have not seen deformity of the breast due to implant contracture with the LOTUS™ breast implant, as is common in silicone implants.
5. Chronic Pain - Pain has not been a complication observed so far in our experience with the LOTUS™ breast implant, but theoretically it is possible. Two percent of the over 600 patients having had internal mastopexy purse string suture procedures, (frequently used in conjunction with a LOTUS™ breast implant); have complained of a pulling pain from the sutures being too tight. When this does not resolve with time, we have obtained resolution of the pain with simple removal of the suture under local anesthetic.
6. Need for Re-Operation - All plastic surgery operations have the possible need for re-operation or revision. In rare situations it is conceivable that a problem with the LOTUS™ breast implant might require removal. What is more likely though is the need for a second fat grafting session or revision of a mastopexy to achieve greater symmetry or perkiness.

7. Obstruction of Mammograms - Placement of breast implants always adds some degree of difficulty in evaluating subsequent mammograms. In instances of difficulty, other radiologic exams such as ultra-sound or MRI exams can be very helpful. Familiarity with the type and location of the implant usually minimizes any difficulty the radiologist may have evaluating post op mammograms. The LOTUS™ implant is always placed where the breast gland was removed, and on top of the chest wall. Six titanium micro clips are placed around the perimeter to alert a radiologist to the presence of this device, but also remembering to give your surgical history to the radiologist should prevent any confusion.
8. Carcinogenesis - In extremely rare cases it is possible for *silicone breast implants* to cause a rare cancer known as Anaplastic Large Cell Lymphoma (ALCL). ALCL associated with silicone breast implants: https://www.abcactionnews.com/news/national/fda-links-breast-implants-to-rare-cancer-9-deaths. In most cases simple removal of the silicone implant and associated capsule resolves the problem in this localized disease. However, in extremely rare situations there have been deaths due to this cancer. We have no reason to suspect any increased risk of cancer in use of the LOTUS™ breast implant. Studies in animal models, as well as humans have shown P4HB to be very biocompatible, to incorporate into tissues with very little inflammation, and resorb through a process known as "hydrolysis" - in 1.5 to 2 years. The break down products of the P4HB are carbon dioxide and water.
9. Unknown Complications - There may be certain rare complications associated with the use of an absorbable breast implant that are unknown at this time. It may take many years and thousands of patients' use of this new device to know all possible side effects. It is possible that remnants of the scaffold will remain in the newly formed fatty tissue behind the breast for many years. The significance of this is unknown, but unlikely to cause problems due to the biocompatibility of the polymer and its ready integration into healthy healing tissue. In the worst-case scenario, the scaffold would be surgically removed in a procedure similar to silicone explantation.

Disclosures:

Dr. Rehnke is the inventor of the LOTUS™ breast implant. He holds one U.S. patent on the device and has a second patent pending. The ultimate goal is for the broad use of this alternative to the standard silicone breast implant. This would require manufacture and marketing of such a device, which would require clinical trial study of its safety and efficacy prior to approval by the FDA. For now, its early use is governed by the doctor patient relationship between each patient and Dr. Rehnke. This puts more responsibility on each patient and Dr. Rehnke to decide if use of the LOTUS™ breast implant is right in each particular situation.

Should complications from the surgery or LOTUS™ breast implant require revisionary surgery or removal of the implant, the financial responsibility is on the patient according to our office financial policy.

Signature: _____ Date: _____

Witness: _____ Date: _____ Revised 10/18