World First Alternative to Silicone Breast Implants

West Midlands, United Kingdom Aug 25, 2022 (Issuewire.com**)** - On June 23rd Moana Staunton became the first woman to receive a revolutionary new alternative to silicone implants, in Brisbane, Australia. In a world-first procedure, Moana's silicone breast implants were removed and replaced with Lattice Medical's Mattisse prototype implants, which were 3D printed in Germany from polycaprolactone-PCL dissolvable sutures.

Potential profits from this new style of the implant are vast and according to the Breast Implants Global

Market Report 2022, the global breast implants market is expected to grow at an exponential rate, with a predicted compound annual growth rate (CAGR) of 7.43% between 2021 and 2022, alone. Lattice Medical, who has manufactured the implant, has said it is a simple and fast procedure and the technique can be taught to all plastic surgeons.

The safety of silicone implants has been debated since Cronin and Gerow performed the first breast augmentation using a silicone implant, on Timmie Jean Lindsey in 1962. Following a series of successful lawsuits, this led the FDA to restrict silicone implants in April 1992, for use solely in controlled clinical studies

The news of this restriction caused many women around the world to be concerned about the potential dangers of silicone implants, and manufacturers started to develop other types of fillings as an alternative to silicone. In the US the FDA did not authorize the use of any other types of implant fillings. However, two types of revolutionary natural alternative soya and hydrogel implants, marketed as safe enough to eat, were introduced onto the UK market between 1994 and 1995.

Trilucent (soya oil) breast implants were sold in the UK between 1995 and 1999 when they were withdrawn. Following this withdrawal, in the year 2000, women were advised to have their soya-filled breast implants removed. This followed a government-led study that independently confirmed exposure of local tissue to toxic compounds from the soya filling bleeding through the shell or if the implant ruptured.

This subsequently led to the UK withdrawal of Hydrogel implants in Dec 2000 after they were introduced onto the UK market in 1994. However, the withdrawal was due to inadequacies in the manufacturers" biological safety assessments, and no definite risk or evidence to suggest they could be harmful was ever identified by the Medicines and Healthcare Products Regulatory Agency (MHRA). Furthermore, Monobloc CMC Hydrogel implants are still used in other countries such as Holland, where the CE mark is not required.

In November 2006, the FDA approved two manufacturers of silicone gel-filled breast implants, the Allergan Natrelle range, and the Mentor MemoryGel range. Further to the FDA lifting restrictions, the debate regarding the safety of silicone breast implants seemed to be at its end. However, the safety of silicone implants was again brought into question, following the first FDA report of BIA-ALCL in a safety communication for health professionals in 2011.

In 2016 the World Health Organization (WHO), classified cancer as breast implant associated anaplastic large cell lymphoma (BIA-ALCL), and oncologists and plastic surgeons around the world agreed to assist with research. Further to consequent data, on July 24th, 2019 the FDA, BIA-ALCL news release, confirmed Allergan had been requested to voluntarily recall their range of BIOCELL® textured Natrelle breast implants. At that time the FDA had recorded 573 unique cases of BIA-ALCL globally and 33 patient deaths.

To date, 59 women have died following a confirmed BIA-ALCL diagnosis. Although the risk of BIA-ALCL is extremely low and smooth-shelled breast implants are not indicated to cause BIA-ALCL, the race to find a viable solution to today's standard silicone and saline-filled breast implants has become more urgent and profitable. The aim is to provide an alternative that doesn’t entail complicated flap surgery, which is currently the only alternative for women who want breast reconstruction without implants after a mastectomy.

Annabelle Baugh, Founder of Cosmetic Surgery Advancements, has one of the styles of Allergan

textured breast implants that have been withdrawn and regularly posts updates and BIA-ALCL news on her website. She said,

“The fact is no one can know if a medical device is safe until it has been in use for over 20 years, at least. Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) demonstrates this. The styles of Allergan textured breast implants that were withdrawn from worldwide use in July 2019 had been deemed safe and restrictions for use were removed by the FDA in 2006. It is also important to note that according to current scientific data, all women have over 100 times more potential of being diagnosed with breast cancer, than a diagnosis of BIA-ALCL”

With regards to the safety of the new Lattice Medical’s Mattisse implant, she went on to say,

“The Mattisse implants do show great promise, but it is critical to remember that we are still in the early stages of human trials. At this time we don’t know enough to decide if these implants offer a safer alternative to today's standard style of breast implants..”

To understand why this new Lattice Medical’s Mattisse implant is different, you need to understand how breast implants are made. All breast implants, regardless of the filling, have a silicone outer shell, which is why both saline and silicone-filled breast implants have been associated with BIA-ALCL. It is the textured surface of the outer silicone shell, not the filling that is linked to the cause of BIA-ALCL.

Currently the main option, aside from breast implants, for women who want to enlarge their breasts for aesthetic reasons, is breast augmentation with autologous fat transfer. Issues with this method include the unreliability of the results from fat transfer and limitations in the increase of breast size. This is because fat cells can die and be reabsorbed by the body after being injected. Furthermore, women who want breast implants removed and replaced are not usually suitable for fat transfer, as this will not fill out the breast sufficiently, to produce an aesthetically pleasing shape.

The Mattice implant may now offer a viable way to reconstruct or enlarge breasts without the need for a permanent foreign implant to remain in the body. This is due to the scaffold which forms the Mattice implant which either encases a small flap of tissue from the breast area which grows to fill the scaffold or fat cells can be taken via liposuction, and then injected into the scaffold. Over the next 18 months to two years, it is anticipated the scaffold will completely dissolve. Theoretically after this period, the patient's breasts will then be formed from only natural tissue.

When Moana Staunton decided to remove her faulty breast implants she sought the advice of Professor Ung, a breast and endocrine surgeon, and agreed to become the first human patient to trial the Mattice implant. Although the long-term success of this trial can’t be known, Professor Urg believes that if it is successful this could bring about an end to the use of ‘current day’ breast implants.

In an article published by ABC News, Professor Ung said,

"There are literally hundreds of thousands of women out there with silicone implants and silicone implants don't last forever, …This is something that's going to be quite natural for women, it's their own body tissue. And will hopefully never need replacing."

Douglas McGeorge FRCS (Plast) and a past president of the British Association Aeasthetic and Plastic Surgeons (BAAPS), told us,

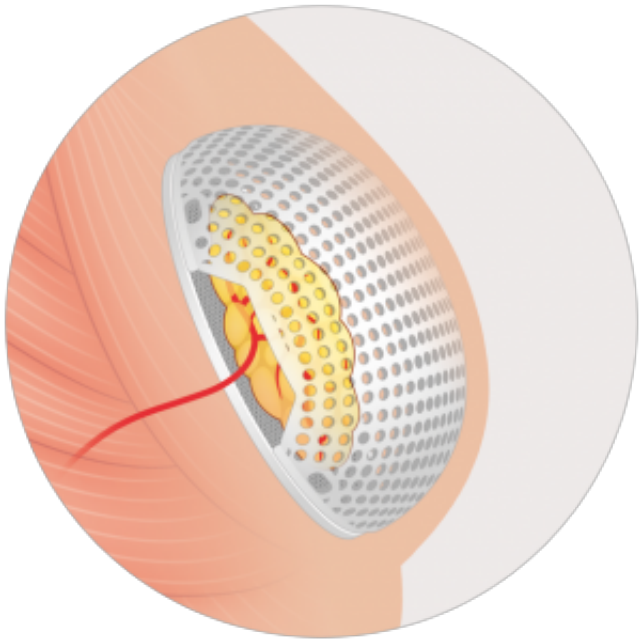
“The absorbable matrix implants are a great concept, but one, certainly to start with, that is best suited

to reconstruction. Use is still very much in its infancy and a lot more research needs to be done before it could replace the conventional options."

With regards to BIA-ALCL, he went on to say,

"ALCL is associated with textured implants, particularly the coarse texturing used by Allergan. Smooth and microtextured implants do not have the same potential risks. Microtextured implants are, perhaps, the best option for patients at present."

Only extensive human trials and further research will determine the safety of this new type of absorbable matrix breast implant. In the same way, the vaginal mesh was deemed safe and is now causing severe complications in some women, it is impossible to know if the implants made from polycaprolactone-PCL dissolvable sutures will cause complications in the future.



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