

Category

Best Startup

Product/Solution Name

MATTISSE

Date of Approval

2022-12-31

Indications

Breast Reconstruction after a total mastectomy

Prophylactic reconstruction

Breast Augmentation

Therapeutic Categories

Breast Cancer

Aesthetics

Background information and need for solution/product

Lattice Medical is a clinical stage start-up, located in Lille, France who successfully raise more than 10 M€ in two rounds.

The company has been founded 5 years ago by 2 M.D., a Plastic Surgeon and an Entrepreneur who met each others ten years ago to develop a tissue engineering technology combining 3D printing, biomaterials to regenerate autologous adipose tissue for soft tissue reconstruction.

Lattice Medical aims to revolutionize breast reconstruction with a silicon free approach to allow self reconstruction.

1 woman on 8 suffer from breast cancer and two hundred and forty thousand of them have a full mastectomy every year for their cancer treatment. And yet, only 20% of women have access to breast reconstruction. The current solutions are not adapted, - silicon implants bear long term risks and autologous surgeries request to undergo several invasive surgeries leading to pain and stigmatizing sequelae.

We introduce a Breast Revolution with the MATTISSE implant, a bioabsorbable tissue engineered chamber, allowing:

- An autologous & natural reconstruction by regenerating small vascularized flap harvested around the breast area
- A full resorption after 18 months
- A single surgery of one hour and half simplifying autologous procedures by avoiding microsurgery.

Once implanted, MATTISSE regenerates a small pedicled fat flap harvested locally in below the breast area (in the 7th & 8th intercoastal area), during three to six months. Once the tissue is fully regenerated, the implant slowly disappear for a full resorption over eighteen months.

The patient recover a full breast with its own tissue, without silicon implant without any donor site sequelae.

Attached Files:

- LATTICE MEDICAL MATTISSE BACKGROUND UNMET NEED SOLUTION.ppsx

History of the development of the solution/product

Lattice Medical has run several successful pre-clinical trials on more than 100 murin and and pigs models, showing strong performance.

We show an adipose tissue regeneration in all the subjects by 90 days thanks to MRI control of the regenerated volume. The regenerated tissue volume is stable other 21 months follow-up after the surgery. The surgical technique is highly reproducible thanks to a pre-operative doppler echography check of the flap vascularization and a simplified procedure for flap reconstruction of one hour. The histology confirms the neo-vascularisation of the tissue and it's stability other time. It also shows that there is less connective fibrotic tissue around the regenerated tissue, thanks to the degradation of the device.

We also run pre-clinical studies to confirm the compatibility of MATTISSE with adjuvant treatment such as radiotherapy.

Lattice Medical also succeed in al GLP safety studies showing our product is safe with no adverse event and a standardize degradation of the biomaterial without any signs of toxicity.

All the preclinical datas have been published in peer-reviewed scientific articles.

We have started a first-in-woman study in Europe last year with the first patients included among 50 patients planned until end of 2024 and will be followed 24 months. Patient inclusion concerns women with a Breast Cancer and requires an immediate reconstruction after a full mastectomy. First results show low pain, complete healing in 1 month and a tissue regeneration in 3 months as expected from our preclinical trials. The study involve 8 centers in Europe (France, Georgia & Spain) such as Institut Gustave Roussy, CHU Lille, AP-HP, CHRU Strasbourg or Sant Pau.

Attached Files:

- LATTICE MEDICAL MATTISSE HISTORY OF DEVELOPMENT.ppsx

Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition

MATTISSE brings a silicon-free solution promoting an easy way for autologous reconstruction. For patients it means a real psychological well-being, positive relationships with oneself, sense of personal development. MATTISSE allows a single surgery of one hour, mastectomy and reconstruction possible at the same time. It's also an improvement of quality of life thanks to less sequelae of the donor site because the removal of the flap is minimal. The full resorption of the device allows a natural and permanent reconstruction with the patient's own tissue.

For the physicians, it means a time reduction surgery of 8 hours for an autologous flap and a full resorption of the device leads to less long-terms complications.

The combination of our implant + flap allows more patient eligible to breast reconstruction thanks to adipose tissue regeneration.

Lattice Medical has developed an innovative manufacturing process of MATTISSE, using 3D printing to create a platform able to produce different shapes, size to adapt the implant to the women's morphology. This printing farm is following medical quality standards and is fully operational in a ISO7 clean room environment. We integrate from the raw material extrusion, to 3D printing, post-processing and sterilization of the product. This production tool is unique and allow an extrem flexibility and versatility.

This industrial platform also give the opportunity to develop other applications for adipose tissue regeneration, for example in deep wound reconstruction with our another device RODIN. This second

device allow the autologous reconstruction of the hypodermia part of a skin after a deep wound caused by burns or trauma. Lattice Medical aims to develop other tissue engineering implants based on its platform in the future.

The CE mark is expected in 2026 and we are actually assessing the FDA requirements under PMA to start an IDE in 2025 for a FDA clearance expected in 2029. We expect a pivotal study involving 300 breast cancer patients in US soil in 22 centers.

Attached Files:

- LATTICE MEDICAL MATTISSE INNOVATIONS BENEFITS.ppsx

Please provide appropriate references (ie Pubmed links)

Scientific Reports volume 10, Article number: 11779 (2020) - <https://www.nature.com/articles/s41598-020-68776-8>

Plastic and Reconstructive Surgery 149(6):p 1251e-1252e, June 2022 - <https://pubmed.ncbi.nlm.nih.gov/35446791/>

Plastic and Reconstructive Surgery - Global Open 10(12):p e4720, December 2022 - <https://pubmed.ncbi.nlm.nih.gov/36569243/>

Polymers 2021, 13(4), 572 - <https://www.mdpi.com/2073-4360/13/4/572>