Breast Implant with Macroporous Shell for Improved Safety and Stability

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**Background & Unmet Need**

- In 2020, there were >193 K breast augmentations and ~138 K breast reconstructions in the US, the majority of which used breast implants.
- In the past, textured breast implants were preferred to smooth implants as they provide greater positional stability, allowing them to be made in more natural shapes.
- Textured implants also reportedly decreased rates of capsular contracture, implant malposition, reoperation, and improved aesthetic outcomes.
- However, textured implants have recently been associated with Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), and many have been recalled from the market.
- As a result, there is a lack of suitable shaped implant alternatives to replace textured implants.
- **Unmet Need:** Breast implant technology that promotes long-term implant positional stability without the use of traditional textured surfaces.

**Technology Overview**

- **The Technology:** A novel silicone breast implant with a macro-well surface architecture for implant positional stability.
- **The Discovery:** Anecdotal observations in revision cranioplasty cases using implants with macro-well surfaces have revealed that soft tissue ingrowth into the cranioplasty implants held them in position.
- By incorporating macro-pores into smooth breast implant shells, capsular tissue can grow into the pores, thereby anchoring the implant to the surrounding tissue securely.
- **PoC Data:** In an *in vivo* rat model, rats receiving the experimental macro-well implants demonstrated ingrowth of soft tissue into the wells.
- Rats implanted with anatomically shaped experimental implants, consisting of soft silicone gel inside a macro-well shell, demonstrated decreased rotation over a four-week period compared to those receiving smooth implants.

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**Patents:**
- PCT Application Filed

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**Cornell Reference:**
- D-10273
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**Technology Applications**
- Breast implants with improved positional stability and more natural shape
- Soft tissue implants for other parts of the body with improved positional stability and improved safety profile

**Technology Advantages**
- May facilitate rapid tissue ingrowth to promote positional and rotational stability
- Shape may be more alike to native breast anatomy
- Potential to reduce long-term capsular contracture by disrupting planar myofibroblast arrangement

**Supporting Data / Figures**

![Figure 1: Left: Three-dimensional rendering of breast implant with macropores using Fusion 3D rendering software. Right: Experimental implants demonstrated lower rotation in an in vivo rat model compared to smooth implants.](image)

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