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Ossicular Prosthesis and Method and System for Manufacturing Same

Key Investigator
- Jeffrey Hirsch
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Field
- Otology
- Prosthetics

Technology
- Ossicular Prosthesis
- Conductive Hearing Loss
- Ossicular Chain Reconstruction

Advantages
- Custom-fit to patient's anatomy
- Reduced surgical time
- Improved hearing outcomes

Status
Available for licensing

Patent Status
US 10,646,331 B2

UMB Docket Reference
JH-2017-053

External Reference
Global Partial Ossicular Replacement Prostheses Market Analysis, Size, Share, Growth, Trends & Forecast, 2019 - 2027," Transparency Market Research.

Summary
This patent describes a personalized medical device, specifically an ossicular prosthesis manufactured via 3D printing, tailored to individual anatomical data from CT scans. The market for such prostheses is growing, driven by the aging population and technological advancements. The innovation's novelty lies in its custom-fit design, improving surgical outcomes and addressing the unmet need for personalized treatment in otology.

Market
The Partial Ossicular Replacement Prostheses (PORP) market is a specialized segment focusing on the treatment of hearing loss through surgical intervention. The global PORP market is projected to reach a valuation of approximately $924 million by the end of 2027. This growth trajectory is underpinned by a compound annual growth rate (CAGR) of around 6% during the forecast period from 2019 to 2027.

The expansion of the PORP market is driven by several factors, including the rising prevalence of hearing loss, the aging population, and technological advancements in prostheses materials and design. Titanium and hydroxyapatite are the leading materials used in these prostheses, with titanium being particularly favored for its excellent biocompatibility and hydroxyapatite for its rigidity and effective sound transfer.

The market is well-established in North America due to its advanced healthcare infrastructure and high incidence of hearing loss conditions. However, the Asia Pacific region is expected to witness significant growth, propelled by an increasing population and a rise in healthcare expenditures.

Despite the advancements, there remain unmet needs within the market. These include the development of prostheses that can be easily adjusted post-surgery, improved integration with existing biological structures, and solutions for patients with complex anatomical challenges. The patented innovation in question addresses these gaps by offering novel designs or materials that enhance the efficacy and comfort of ossicular replacement surgeries.

Technology
The patent represents a novel treatment of conductive hearing loss due to ossicular chain defects. The innovation combines medical imaging and additive manufacturing to create personalized prosthetics. Using CT scans to capture the intricate details of a patient's middle ear anatomy, the system can identify specific landmarks within the ossicles. These landmarks, despite their variability among individuals, serve as the foundation for generating a 3D model of a prosthesis that is not just a generic fit but is designed to the exact specifications of the patient's anatomy.

The key features of this technology include a linear trough and a cup, which are designed to align with the manubrium of the malleus and fit over the capitulum of the stapes, respectively. A connecting strut extends between the cup and the trough, forming the completed ossicular prosthetic model. This model is then attached to a sinter box, which is used in the 3D printing process to create the final, patient-specific prosthesis. The materials and components used in the manufacturing process are biocompatible, ensuring that the prosthesis can be safely implanted without adverse reactions

The advantages of this approach are manifold. The precision of the fit reduces the rate of postoperative displacement, a common issue with traditional prostheses. This custom fit also leads to improved hearing outcomes, as the prosthesis can more effectively transmit sound vibrations. Moreover, by eliminating the need for intraoperative sizing, the technology reduces surgical time and the costs associated with longer procedures.

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