



AuriNovo™ 3D-Bioprinted Ear Implant: A First-of-its-kind Approach for Ear Reconstruction in Microtia



AuriNovo™ is designed to provide a treatment alternative to synthetic materials and rib cartilage grafts traditionally used to reconstruct the outer ear in patients with microtia. The US Food and Drug Administration (FDA) granted AuriNovo™ Orphan Drug and Rare Pediatric Disease Designation for treatment of microtia and has allowed 3DBio to initiate the first clinical trial using AuriNovo™. 3DBio Therapeutics' first-of-its-kind investigational living tissue ear implant, AuriNovo™, is a patient-specific implant for surgical reconstruction of the outer ear in people born with microtia grades II-IV which affects ~1,500^{1,2,3} births per year in the US. AuriNovo™ has not received FDA approval.

AuriNovo™ is created on-demand for patients using 3DBio's pioneering approach which develops living tissue implants with structural and functional integrity using novel 3D-bioprinting and materials technologies.

THE PATIENT JOURNEY



Patient's own chondrocytes are obtained from a biopsy from the patient's impacted ear



Cells are expanded in a specialized cell culture system



Patient's cells are mixed with ColVivo™ collagen-based bio-ink



Patient's AuriNovo™ is surrounded by a protective biodegradable Overshell to provide early structural support and implanted in the patient. The Overshell is resorbed by the body over time

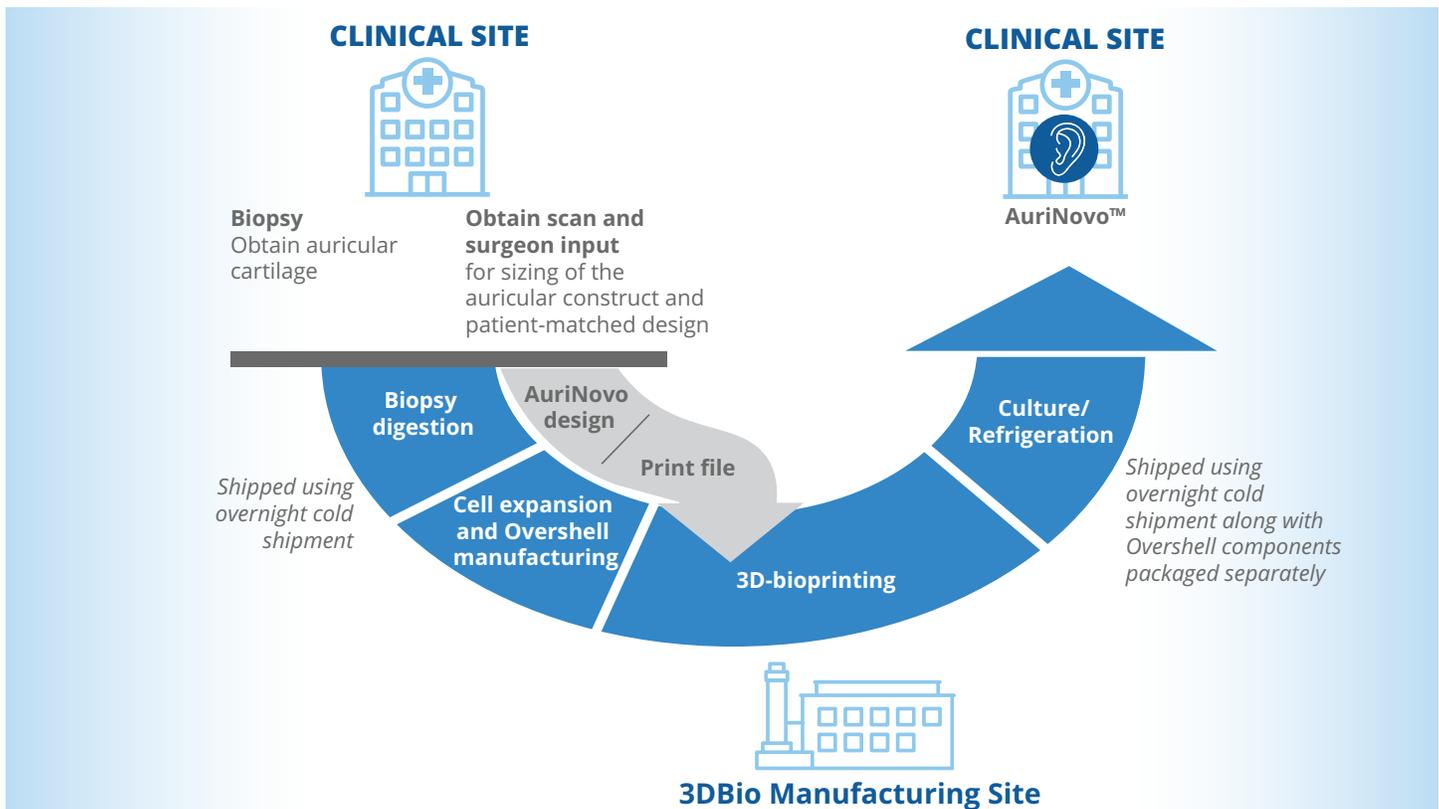


Bio-ink is shaped, using the GMPrint™ 3D-bioprinter, into a living AuriNovo™ implant mirroring the size and shape of the patient's opposite ear



The implanted ear matures with time and develops the characteristics of a native ear, including flexibility, elasticity and a typical "look and feel"

AURINOVO™ MANUFACTURING PROCESS



BREAKTHROUGH ADVANTAGES OF AURINOVO™

If AurinoVo™ is approved by the FDA for ear reconstruction, patients with microtia and their families could benefit from an unprecedented development in regenerative medicine. AurinoVo™ is designed:

- As a biocompatible implant that avoids implant rejection
- For reconstruction with outpatient surgical procedure
- For use in even young children
- To provide a reconstructed ear with natural flexibility and the look and feel of a natural ear expected to last a lifetime
- To avoid painful, complicated rib cartilage harvests—required for a current standard of care

ONGOING CLINICAL TRIAL

3DBio Therapeutics is currently conducting a Phase 1/2a clinical trial of AurinoVo™ for use in auricular reconstruction of microtic ears. The study will collect safety data, efficacy (aesthetic outcome) data, and evaluate technical, logistical, surgical and post-surgical care aspects of AurinoVo™ reconstruction. Subject will be followed for up to five years.

1 Luquetti, D.V., et al., Microtia: epidemiology and genetics. *American Journal of Medical Genetics Part A*, 2012. 158(1): p. 124-139.

2 Luquetti, D.V., E. Leoncini, and P. Mastroiacovo, Microtia-anotia: a global review of prevalence rates. *Birth Defects Res A Clin Mol Teratol*, 2011. 91(9): p. 813-22.

3 Internal 3DBio Therapeutics Market Research Report

For more information on the trial, please see clinicaltrials.gov, (NCT04399239). To learn more about 3DBio Therapeutics, please visit [3DBioCorp.com](https://www.3dbio.com).