

New Device Brings Innovation to Ear Hygiene

Clear Ear uses Proto Labs' rapid injection molding service for pilot production of its Oto-Tip.

Clear Ear Inc., a San Francisco-based consumer health startup spun off from a Stanford University class project, is offering a new way to do just what the company's name suggests.

Lily Truong, co-founder and CEO of Clear Ear, was a student in Stanford's biodesign program when the group she was working with discovered that a leading cause of poor ear health is improper earwax management. Hearing loss and hearing aid failure both can result from excess earwax or cerumen, the company explains.

Clear Ear's solution is the Oto-Tip, a patented new device for safe, daily ear cleaning. The small, handheld device features an automated, spinning swab with a soft, flexible tip that directs wax out of the ear canal. A built-in safety cap on the wand-like device prevents the swab from going too far into the ear and from pushing wax deeper into it, which the company says is a common mistake.

The product's design also addresses concerns on a personal level for Truong, who now has a master's degree in biomechanical engineering from Stanford. "I've had firsthand experience with hearing impairment after my mother went deaf in her left ear years ago, and have seen that ear health is a space that hasn't seen a lot of innovation," Truong says. The unique device is one of the drivers behind Clear Ear's mission of "making ears happier."

Clear Ear has used Proto Labs' injection molding service to produce parts for the Oto-Tip, according to Leland Stock, the company's director of research and development. The assembly includes four external parts that require a high finish and two internal parts that need to meet high standards on tolerance and fit to interface with electrical components.

The company has pre-sold 1,250 Oto-Tips through a crowdfunding campaign on Indiegogo and recently began shipping them to backers, Truong says.



Clear Ear's Oto-Tip device can be used as an alternative to cotton swabs during earwax removal. Photo courtesy of Clear Ear, clearearinc.com.

"It was just what we needed to get our manufacturing up and running quickly," Truong says of the injection-molded parts. "Now, as we start looking into full production, we can take along all the learning from the Proto Labs' injection molding process with us."

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Truong founded Clear Ear in 2011 with Dr. Vandana Jain, a surgeon she met at Stanford's biodesign program. "The program brings together multidisciplinary team members to train [students] in the process of finding unmet clinical needs, creating solutions to solve those needs and bringing them to market," describes Truong.

The company went into Stanford's StartX Med accelerator after spinning off from the university. Clear Ear is one of 25 companies to enter the competitive StartX program, which focuses on "accelerating the development of Stanford's top entrepreneurs through experiential education and collective intelligence," according to the program's website.

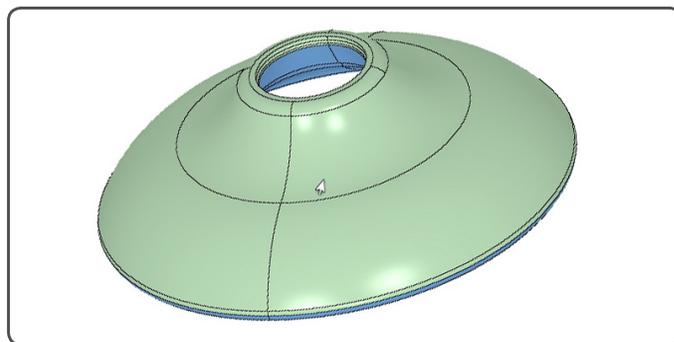
"They were instrumental in getting us off the ground, and being able to tap into the amazing support network of StartX founders has helped us get to the stage of commercialization of products that we are now," Truong says of the accelerator program.

The company's goal is to make good ear hygiene less of a struggle, Truong says. "We all want our ears to feel clean, healthy and happy," Truong says. "However, every day millions of people around the world clean their ears the wrong way. People use various ways to clean their ears like cotton swabs, ear candling and bobby pins, which can do more harm than good. Everyone from doctors to the media has said that you shouldn't put things deep into your ears."

Cotton swabs can push earwax deeper into the ear canal and cause plugs, according to the company. The buildup can cause itchiness, dizziness, pain and ringing in the ears. Swabs also can puncture the eardrum and cause dryness in the ear canal, which leads to using more swabs to relieve itching in the canal. Oto-Tip is nonabrasive and avoids pushing wax deeper into the ear and the risk of piercing the eardrum, according to Clear Ear. It's also reusable and more eco-friendly than swabs.

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The first set of injection-molded parts that Proto Labs produced for Clear Ear made possible initial beta testing of the product with early adopters and partners. Their feedback will "help us make informed decisions about how to move forward towards the best-performing product and also to design it for higher-scale production in the future," Stock says.



Proto Labs molded a thermoplastic elastomer safety cap, shown here in 3D CAD form, which prevents the swab from going too far into the ear and from pushing wax deeper into it. Image courtesy of Clear Ear, clearearinc.com.



An automated, spinning swab with a soft, flexible tip directs wax out of the ear canal. Photo courtesy of Clear Ear, clearearinc.com.

Before going to Proto Labs, Stock says, the company tried rapid prototyping processes elsewhere, including 3D-printed parts that had painted external surfaces. "But it can only take you so far because of the limits of tolerances as well as material performance," explains Stock. "We had to go to injection molding to produce something we could send out to early adopters." Clear Ear has used polycarbonate for most of the plastic parts that Proto Labs has injection molded for the Oto-Tip, Stock said. The swab, or ear interface, is made of thermoplastic polyurethane (TPU) plastic.

Besides transitioning from early 3D printing to injection molding at Proto Labs, another major prototyping update involved switching from AA batteries to AAA, to reduce the Oto-Tip's size and accommodate internal feature changes, Stock says.

Working through changes with Proto Labs' engineers was particularly beneficial, says Stock.

"I like the design analysis feature on the automated quoting system," he says. "It gives you an idea of where there may be big issues to address right off the bat. Also, talking to the customer service engineer about what I needed out of the part and the features I needed or didn't need was really helpful because he could make adjustments to customize the part."