FORMLABS WHITE PAPER:

3D Printing Custom Silicone Ear Molds

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Abstract

Custom ear molds provide a highly secure and comfortable fit for applications like hearing aids, musician in-ear monitors, high-end earphones, and hearing protection–but manufacturing customized pieces can be a challenge.

With digital scanning technology and software, collecting and modifying the organic shape of an individual's unique ear canal is simplified, and with 3D printing, fabrication follows suit. Digital manufacturing provides greater control and accuracy compared to traditional mold production, significantly reducing the number of errors and remakes.

Traditionally, digital workflows have been cost-prohibitive to all but a handful of large ear mold laboratories. Now, with technologies like the the Form 3B, an advanced desktop 3D printer optimized for biocompatible materials, ear mold labs of all sizes are able to shift manufacturing soft silicone ear molds to a digital workflow.

In partnership with **The Listening Stack**, this white paper outlines the process for making custom silicone ear molds using a Formlabs SLA printer and Clear Resin. This workflow will also work with our BioMed Clear Resin as well. Since integrating this digital workflow, The Listening Stack owner Justin Stack estimates that the company has seen a 40 percent reduction in remakes, resulting in considerable cost and time savings for his business.

Introduction

Audiology applications are a natural fit for mass customization with 3D printing. The inside of every person's ear is composed of extremely unique organic shapes and curves. In-ear molds must be a perfect fit to assure the optimal seal and performance of the final device.

Traditionally, custom in-ear molds are manufactured using a laborious process that requires several different casting and hand-fabrication steps. In the last decade, making a custom mold has largely shifted to a digital workflow. Digitally editing and 3D printing each custom mold allows for more consistent quality, accuracy, and better product management.

Many larger ear mold laboratories already use 3D printing in their moldmaking workflows. While the process is relatively established, the cost of high-precision printers has made additive technology inaccessible for smaller ear mold labs. As a result, many labs still use the traditional, impression casting approach, while others opt to outsource manufacturing.

This white paper outlines the process for casting a custom silicone ear mold from a shell that has been printed on a Formlabs stereolithography (SLA) 3D printer. This process is successfully used by our users like The Listening Stack, an ear mold lab and hearing aid center in California that provides patients with hearing aids, custom ear protection, and in-ear monitors.

Fig. 1: A silicone ear mold cast from a print created on a Formlabs SLA printer.

Fig. 2: A soft and a hard ear mold.

Transitioning to Digital Ear Mold Production

Custom ear molds come in several different styles and materials, depending on the application, and typically fall into either a hard (usually acrylic) or soft (usually silicone) category. 3D printing provides efficiencies for making both types of molds through two slightly different printing techniques.

Traditionally, custom ear molds and shells are manufactured by manually altering the ear impression though subtractive (material removal, sanding, and polishing) and additive (dipping in wax) methods. The impression is then used as a master to make a negative cast from another material, which is then filled with the final mold material. If the mold is a hard, acrylic material, it is then post-cured in this form in a UV oven to harden. If it is soft, silicone material, it is post-cured in a pressure polymerization unit. The process is laborious, time intensive, and requires specialty skills and experience to ensure a consistently high-quality product. As the process is done largely by hand, human error makes consistency a challenge, and remakes are commonplace.

With 3D printing, an impression can be scanned and digitally altered on a computer, reducing the room for human error and physical effort. Scans can be saved and re-altered, instead of collecting a new impression to fix a mistake or make a new mold. The files are then 3D printed as a hard mold for direct use in the ear, or as a shell for the injection of a softer material, which is then used as the final product.

The final product is more accurate and consistent, thus requiring fewer remakes and providing more control for the technician.

The benefits of a digital workflow extend into overall business efficiencies as well, as files can be easily stored for many years and require no physical storage or maintenance. This allows for optimal patient record keeping and economies of scale when more than one mold will be produced.

How to Use SLA to Manufacture Custom Soft Ear Molds

SLA 3D printers such as the Form 3B provide new opportunities for ear mold labs that want to transition from hand- fabrication processes to more accurate and consistent digital workflows. The Listening Stack is already using the their printer to manufacture nearly all of their custom hearing protection molds in-house.

The following sections outline The Listening Stack's end-to-end process for manufacturing soft full shell ear molds.

This process uses a method often referred to as the "eggshell technique," where companies print a shelled, hollow version of an ear mold, which is then injected with silicone to produce a custom, soft ear mold. The printed cast is cracked away from the injected silicone ear mold, like cracking an eggshell from a hardboiled egg.

Fig. 3: Ear molds cast with a Formlabs printer

Process Workflow

1. COLLECTING AN IMPRESSION

An integral part of producing any custom in-ear mold is to collect an impression of the inside of a patient's ear. To do this, an audiologist or hearing dispenser injects an impression material, typically a type of liquid/powder mix or silicone, into the ear using a syringe. The material is usually blocked from extending too far into the canal with an otoblock, which is a small piece of foam or cotton that is placed in the ear prior to the injection. Once injected, the material hardens within three to five minutes and the impression can be pulled out.

> **Warning!** Taking an impression is a regulated process, and an audiologist or hearing dispenser must be licensed to do so. While DIY impression kits are available, they are often a different style and quality from an impression performed by a professional, and have the potential to cause inadvertent damage to the eardrum.

Fig. 4: Collecting an ear impression.

Fig. 5: Scanning the ear impressions using a 3Shape H600 scanner.

2. SCANNING THE IMPRESSION

Place the impression into a 3D scanner, where its shape will be scanned in as little as 30 seconds. Scanning transfers the physical geometry of the impression into the computer as a digital file.

Due to the small feature size and organic shape of impressions, ear mold labs use scanners designed for this specific application. 3Shape and SmartOptics are two of the leading audiology scanner brands. The digital file will still be in the raw form of the ear impression, which then needs to be edited for the specific ear mold application.

3. DESIGNING THE EAR MOLD

Edit the digital file using software designed specifically to edit ear molds. Use the software tools to hollow and smooth sections of the model, cut channels, and add material as needed. For printing a shell for the injection of a soft mold material, hollow the file and specify the shell wall thickness (typically between 0.5 and 0.8 mm). For hearing protection with additional parts, like decibel filters for musician ear plugs, model the shape of the filter into the shell, so that a cavity is left when the file is printed.

There are a handful of different software packages available, a few common packages are 3Shape's EarMouldDesigner and Cyfex's Secret Ear Designer. Although software integration will be new for a lab that is currently using a traditional workflow, software training is available and digital interfaces are designed to be intuitive and parallel the steps in traditional processes.

Fig. 6: Editing the file in 3Shape EarMouldDesigner audiology software.

What exactly needs to be edited from the original impression?

An optimally-fit ear mold rarely takes the exact shape as the original impression. Any inconsistent or rough sections from the impression are smoothed out and material is often added so that the overall thickness is increased to ensure a tight fit. This serves the same purpose as adding wax layers to the impression in the traditional manufacturing process, which increases the overall volume prior to making the final cast. In addition, if the shell is to be used for the injection of another material, as is in this process example, the mold must be hollow and small drain holes are added throughout the shell to allow for resin to escape after printing and air/silicone to escape during the injection. An injection cone is added in a carefully chosen location to allow for easy injection of the shell, as well as a potential support for printing as an alternative to using the PreForm-generated supports. Each shell can have an ID name and identifiers added for tracking and distinguishing between left and right ear molds.

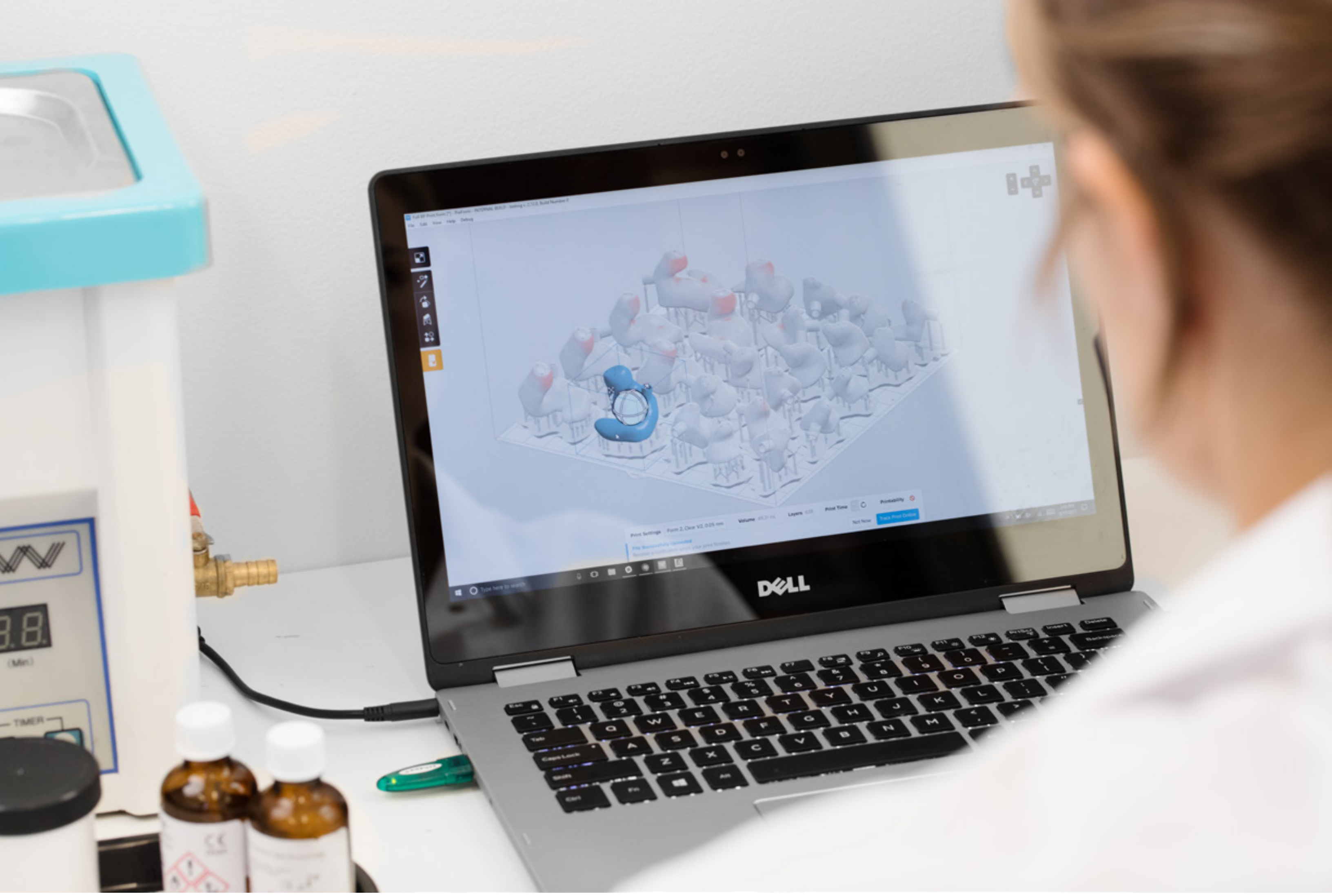


Fig. 7: Editing the file in PreForm.

4. PREPARING TO PRINT

Export the file from the ear mold software as an STL file and upload it into **PreForm**, the free software that prepares a file for printing on Formlabs 3D printers. Simply select the correct orientation using the surface selecting tool, and generate and edit supports as needed. It is imperative to ensure that the 'Build Internal Supports' selection is unchecked, to ensure internal supports do not fill the hollowed shell.

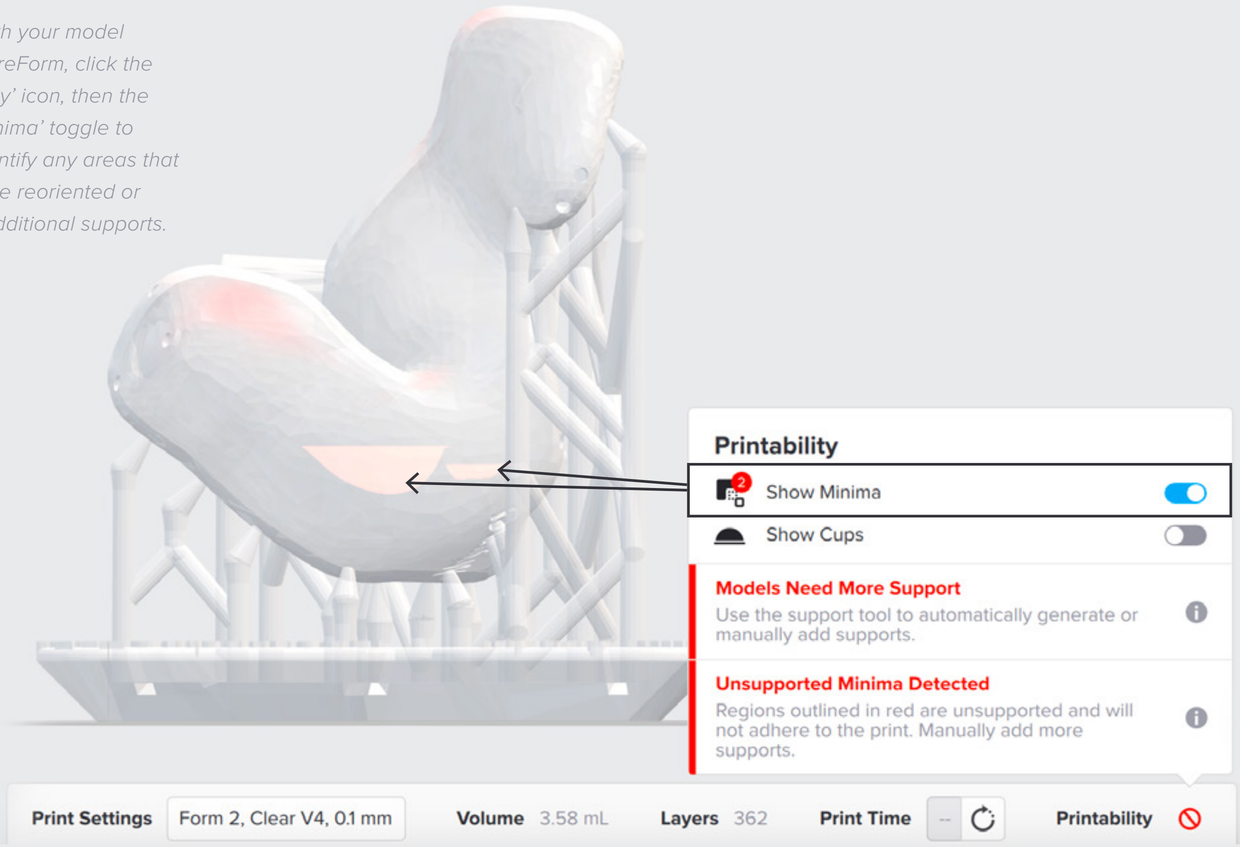
Fig. 8: Schematic of a model's layers building and an internal feature that cannot have supports.

Orientation is key for successfully 3D printing the organic shapes of ear molds. With SLA printing, it is important to ensure that each printed layer is adequately supported by a previously printed layer. If a feature is not attached to a support tip or a previously printed layer, it will fail to print. This can often be a concern with overhangs and internal features, when an unsupported feature overhangs below the connecting point.

An unsupported location is often called a 'print island,' as the location looks like a floating island when the part is scrolled through using the layer-by-layer slider in PreForm. PreForm can now automatically identify unsupported print islands, also called "minima." With your model open in PreForm, click the 'Printability' icon and two options will appear: 'Show minima' and 'Show cups.' Click the 'Show minima' toggle to highlight any unsupported minima. Using this feature, you can easily identify any areas of the model that need to be reoriented or require additional supports.

Print islands are typically resolved by building a support below the location, which works for external features. However, internal components must be support-free, so the parts must instead be correctly oriented to avoid the existence of any internal print islands.

Fig. 9: With your model open in PreForm, click the 'Printability' icon, then the 'Show minima' toggle to easily identify any areas that need to be reoriented or require additional supports.



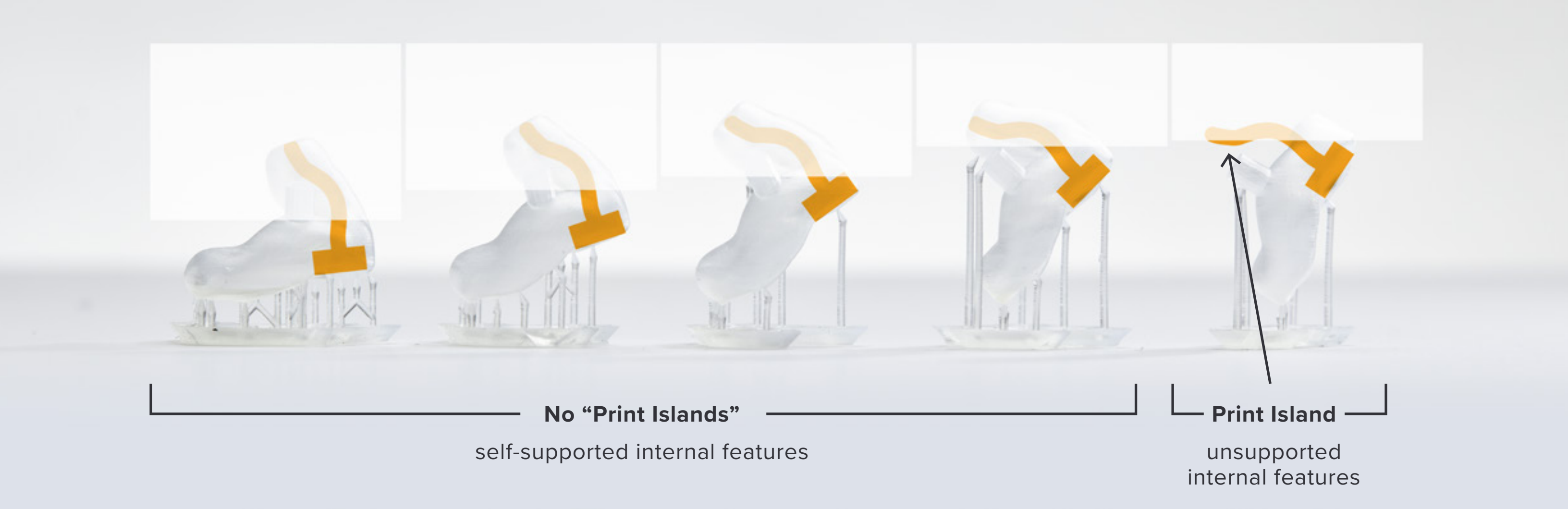


Fig. 10: Each of these five prints are the same, but the orientation can determine the print success. The four prints on the left will print without issue, but the fifth print is oriented in such a way that the internal feature creates a print island.

Formlabs Design Guide outlines general design guidelines for orientation, but orientations of organic shapes such as these are often quickly learned through experience printing different styles of molds.

PreForm generates supports that are optimized for a successful print, but it is also possible to print directly on the build platform, if a part's geometry allows. The injection cone can be positioned on the part in a location that supports the print, similar to a support. This can work as long as there are no print islands (on the external or internal features) and no extensive overhangs, which PreForm identifies in a shade of bright red. Also note that using the injection cone as the support limits the injection cone placement to a location that accommodates for these geometry limitations. If there is a specific location for optimal injection, it may not line up with the placement for optimal support.

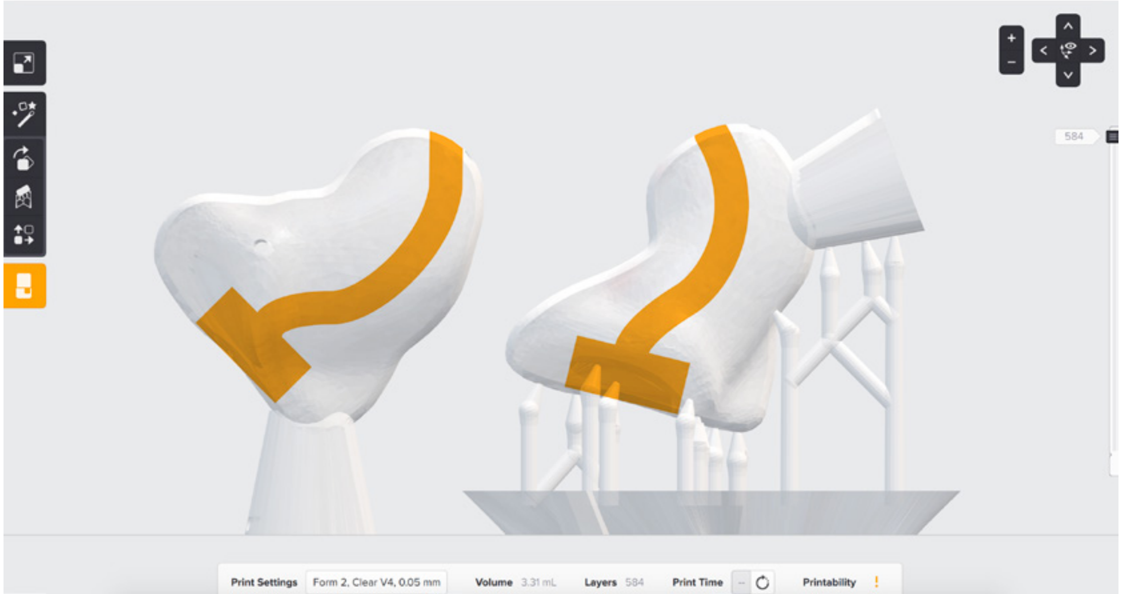


Fig. 11: On the left, an ear mold shell that successfully prints using the injection cone as the support, and on the right, the same ear mold shell with the injection cone in a different location, supported on PreForm-generated supports .

5. 3D PRINTING

Once the file is ready in PreForm, load your printer with a Standard Clear Resin cartridge and tank. Formlabs' Standard Resins produce high quality prints, as the uncured resin has relatively low viscosity for ease of cleaning out internal cavities and the final print material has optimal mechanical properties for shell removal after the silicone injection. A full build platform will take between two and five hours to print at a recommended layer height of 100 microns, but print time will of course vary depending on the mold geometries and shell styles.

Formlabs also offers a biocompatible material suited for ear molds called BioMed Clear Resin. This powerful material allows manufacturers to print earmoulds, shells, and eartips with a impact-resistant hard acrylic bio-compatible material. To learn more, visit our **materials page**.

"The quality of BioMed Clear resin at 100um on the Form3B is amazing! All the embossed names come out perfect, and overall surface quality is great.

You guys nailed it"

Justin Stack
Founder of The Listening Stack

Fig. 12: This full build platform of ear mold shells printed in about 3.5 hours at 100 micron layers.

6. CLEANING THE 3D PRINTED PARTS

Visually inspect the printed parts to ensure that there were no failures, and then dip and agitate the parts in an isopropyl alcohol (IPA) bath. After a first rinse, put the shells loosely in the basket of a Form Wash filled with clean IPA, and wash the parts for 15 minutes. Depending on the shell geometry and drain hole size (a drain hole size of at least 1 mm in diameter is recommended for ease of cleaning), the shells may also need to be syringed with IPA.

Fig. 13: Cleaning the prints in a Form Wash.

Fig. 14: Injecting the print with IPA to remove any uncured resin.

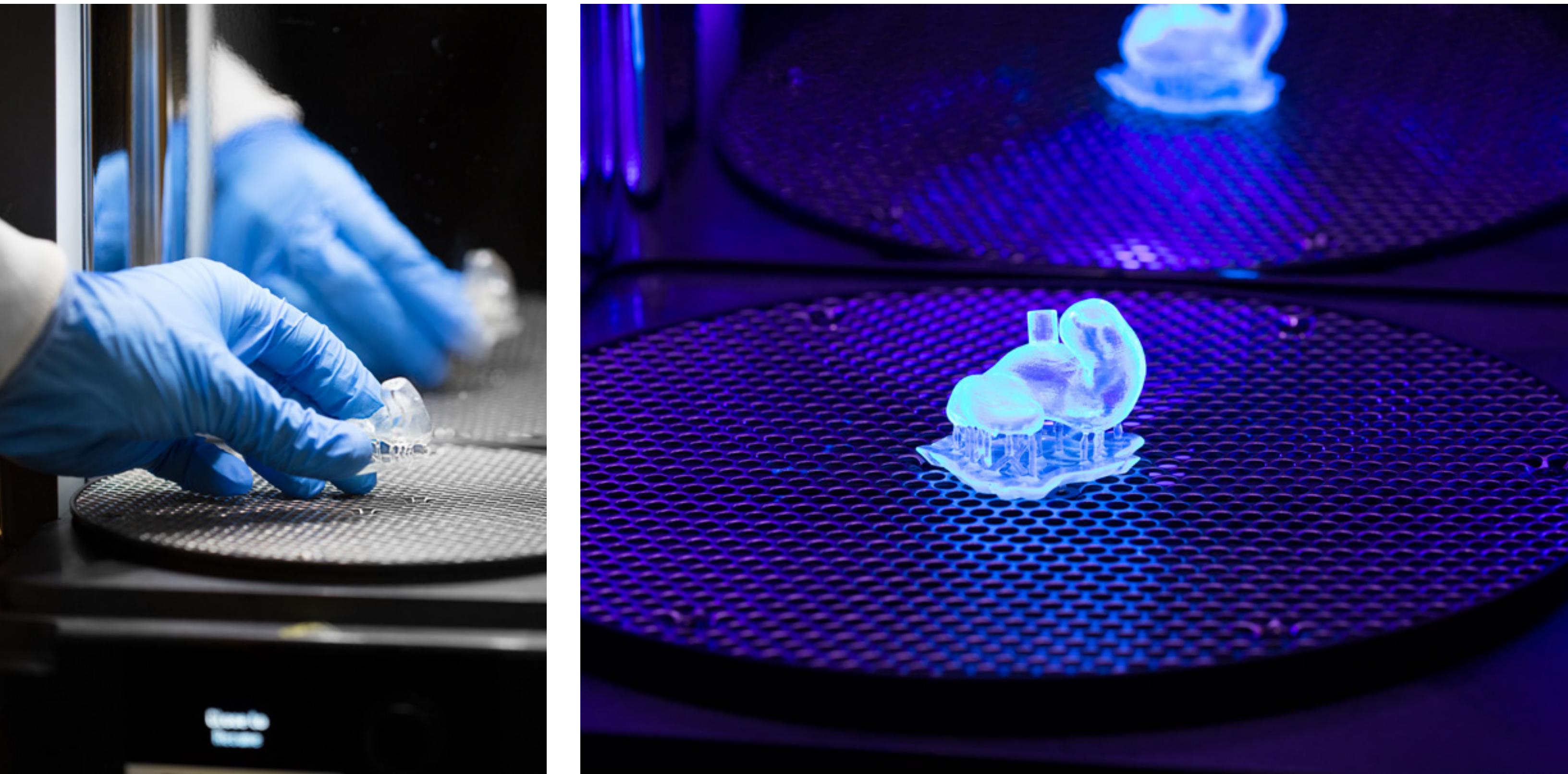
If washing manually, be sure to thoroughly agitate the parts or use an ultrasonic bath to ensure all uncured resin is removed.

Any resin that is left on the inside surface of the shell can lead to inaccurate shell thicknesses when the prints are post-cured, or a sticky residue if the prints are not fully cured, which impedes the final silicone mold's quality. To ensure all residual liquid is removed, blow the printed shells with compressed air after washing.

7. POST-CURING THE PRINTED PARTS

Once the shells have been sufficiently washed and dried, post-cure the parts for at least 15 minutes at 45–60 °C. Although post-curing is not required for Formlabs' Standard Resins, it is beneficial in this process to ensure that any residual resin potentially trapped inside of the print is fully post-cured and that the silicone injection will be smooth. Post-curing can also increase the brittleness of a printed material, which is beneficial in this application for the shell removal later in the process. Due to the organic shape of ear molds, it is necessary to post-cure with full rotation of the parts to ensure all areas of the shell get fully post-cured. Formlabs' Form Cure automatically rotates parts with its turntable and works well for this application. For static post-curing solutions you may need to flip or rotate the part midway to achieve an even post-cure.

Fig. 15: Post-curing the final prints with Form Cure.



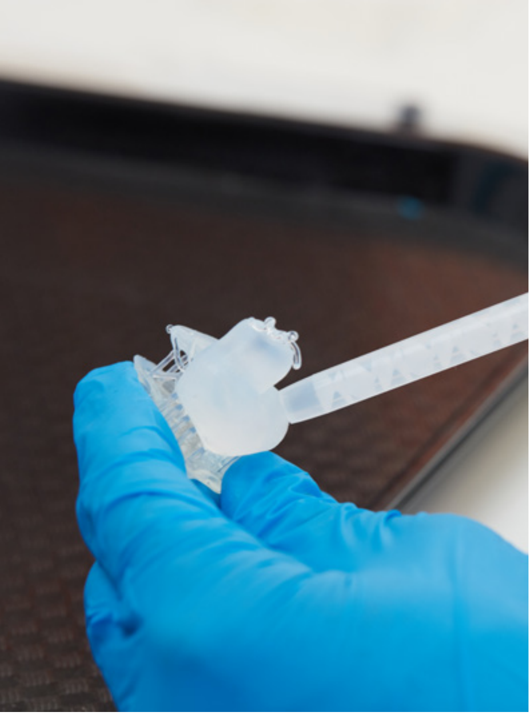


Fig. 16: Injecting the printed shell with BioPor® AB 40 Shore silicone by Dreve.

Fig. 17: The ear mold on the left was post-cured in a Form Cure, without pressure. Tiny bubbles throughout the silicone give the ear mold a slightly opaque appearance. The ear mold on the right was pressurized while the silicone cured, so there are no bubbles in the ear mold.

8. INJECTING THE PRINTED SHELL

The 3D printed shells are now ready for silicone injection.

Load the material cartridge into an injection gun, and attach a mixing tip–unique to the material–to the injection cartridge. The mixing tips are necessary to ensure the two-part silicone is adequately mixed prior to being injected. Inject the silicone into each shell slowly, ensuring all gaps and voids are filled.

The injection silicone is in an airtight cartridge and most air bubbles should escape from the shell during injection, but micro air bubbles that are nearly invisible to the human eye can get trapped in the mold. Small bubbles can also form on the outer surface of the mold if there is any uncured resin on the inside surface of the shell. For the highest quality and most resilient product, remove these air bubbles by placing the cast, immediately after injection, in a pressure pot at 40–60 psi for 25–30 minutes. Household pressure cookers usually cannot safely reach this pressure, so industrial equipment like Dreve's Polymax pressure polymerization units must be used. This is the same equipment and process step that is typically used for the traditional, indirect silicone ear mold casting manufacturing method. The pressure will push any trapped bubbles out of the silicone.

Silicone cures faster with increased temperature. Raise the temperature while pressuring (if a given pressure pot has that functionality) to increase the speed of curing. If you're not using a pressure pot, place the cast in a Form Cure for five minutes at 60 C to fully cure the silicone.

If the parts have supports, it can be helpful to remove the supports prior to injection using the flush cutters that are part of the **Formlabs Finish Kit**. This can make it easier to visually see how the printed shell is being filled, and if there are any air bubbles being formed. However, it can also be easier to hold the print for injection with the supports still attached. The timing of support removal is largely dependant on personal preference and how well the particular shell geometry injects.

Fig. 18: Removing supports using flush cutters

What is the injection material?

Soft ear molds are typically made with a biocompatible, audiology-specific silicone, although other materials are also available. The injection silicones come in two-part cartridges that are mixed while the silicone is pushed through the injection. Many different types of silicones can be purchased, and the main differences include its hardness, color, and opacity. The hardness of a silicone is measured in terms of Shore hardness. A typical Shore hardness for soft, custom ear molds varies between 20 and 70 Shore A. The lower the number, the softer the material, while the letter represents the scale of the durometer test (A is for softer materials, D is for harder materials). Common ear mold silicone manufacturers include Detax and Dreve.

9. CRACKING THE SHELL

After the silicone has fully cured, the shell is ready to be removed. Cracking the shell can be done through a number of methods, and is typically initiated by compressing the cast in a press or with pliers. Remove the pieces by hand or with tweezers. Repeat these two steps until all pieces are removed.

Note: This step must be done very carefully to ensure that the soft silicone is not damaged during shell removal, as shell pieces can pierce into or rip the silicone mold. Through experience, mold laboratories develop techniques for the most efficient and effective shell removal. As is expected, different mold shapes present different approaches for shell removal and cracking techniques. Silicone hearing protection with decibel filters or internal channels have a unique step in the shell removal, as the internally-printed components must be carefully pulled out of the silicone mold.

If the silicone mold still comes out sticky, the silicone has not fully cured (likely due to uncured resin left in the printed shell, which can inhibit the silicone from curing). Place the silicone ear mold in a Form Cure for 5-10 minutes at 60 C to complete the curing. Alternatively, cure the silicone by leaving the ear mold in ambient conditions for 8-12 hours. This additional curing is usually not required, and can be avoided with an optimal cleaning regimen.

Fig. 19: Cracking and removing the shell from the ear mold.

10. FINISHING THE MOLD

After the shell is removed, inspect the mold for any major defects that would not be repairable through finishing. If all looks good, the mold is ready to be finished. Use flush cutters to carefully cut the small pieces of silicone that bulged through the air holes during injection and the silicone piece left over from the injection cone from the mold. Then, as applicable for the optimal surface finish, grind, sand, and buff the mold until all surfaces are smooth.

A desktop lathe and/or flex-shaft dremel is typically used to buff the mold, and variable speed is essential for optimal control. Choose burs, bits, and cutters that are specific to finishing a soft, malleable material like silicone; medium-grit sandpaper and grinding caps work well, while large-pitched cutters tend to just move the silicone around without removing material. Recommended finishing tools can typically be sourced from audiology material manufacturers and suppliers. The Listening Stack sources all of their finishing tools from US Supplier, Warner Tech-Care Products, LLC. Due to the malleability of silicone, the material is relatively difficult to finish, and an error can easily lead to tears during this step, so optimal tools are a necessity. Silicone also attracts dirt and dust easily, so the less finishing required, the better. Formlabs printers prints have a high quality surface finish straight off the printer, so sanding is typically only needed on the locations where silicone pieces were cut from the ear mold, and should only take a few minutes.

Fig. 20: Finishing the silicone ear mold using a medium grit sandpaper on a flex shaft dremel.

Fig. 21: Coating the silicone in Lack B eco finishing lacquer by Dreve.

Once the mold is smooth, coat it in a finishing lacquer to seal the silicone for long term cleanliness and wear; there are many different lacquer types available for different uses and surface finishes. The lacquer can be applied by brushing, dipping, or spraying with an automated coating machine, and serves the purpose of an easy-to-clean, durable, biocompatible surface to rest against the skin. Depending on the type of coating, the finished mold may cure in ambient conditions, or may require additional post-curing.

Fig. 22: Checking the ear mold fit.

11. VERIFYING FIT

Inspect the final product for flaws and test the mold with the patient for fit and hearing protection properties. Assemble the mold with other components, like tubes or electronics, if applicable. After assembly, inspection, and fit check, the patient walks away with their new, custom-fit ear molds.

Conclusion

Manufacturing custom ear molds with 3D printing has revolutionized the audiology space, but accessibility to the technology has been largely limited to a handful of large ear mold laboratories. Smaller laboratories and businesses have either continued to use the traditional manufacturing approach or have outsourced their custom molds from these larger players.

Integrating a Formlabs printer into the manufacturing process has allowed small businesses, like The Listening Stack, to embrace the benefits of a digital workflow and 3D printing custom ear molds. Most importantly, using the digital fabrication workflow in-house saved The Listening stack 40 percent of their manufacturing costs vs. outsourcing, and more than halved the amount of rework they were doing, without a trade-off in quality and for a very low investment.

Transitioning to a digital workflow required training and some costs upfront, but once fully transitioned, Justin estimates that printing in-house with a Formlabs printer has reduced remakes from 20 percent to below 8 percent.

Formlabs printers have reduced remakes

FROM
20%

TO BELOW
8%

Fig. 21: A full build platform with different styles of prints for silicone injection.

The printer's small vat size and affordable price provides benefits to larger scale production laboratories as well. Multiple printers can be integrated into a print farm or **Form Cell**, printing many build platforms at once through an automated, high-throughput process. The Listening Stack hopes to scale up their manufacturing to a Form Cell system in the next few years.

"As demand increases, so will our need for efficient high quality production. I can buy one commercial 3D printer for the same cost as 10 Formlabs printers, and with the Form Cell I don't have to worry about all the tedious work. It's a no brainer for us!"

Justin Stack
Founder of The Listening Stack

Looking to learn more about how desktop SLA 3D printing can impact your lab? Visit the **Formlabs website** and get in touch with our sales team.

Contact Formlabs to learn how desktop SLA can work for your project.

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