#### INSTA-MOLD FEATHERWEIGHT INSTRUCIONTS

### I. PREPARATION

(A checklist of items needed)

#### II. INSTRUCTIONS

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- 2. Insertion of otoblock
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## I PREPARATION

Here's a checklist of items you will need:

- 1. Insta-Mold Featherweight silicone mix Part 'A' and 'B' (Use matching batch #'s)
- 2. Hand Lotion
- 3. Measuring spoons ('A' & 'B')
- 4. Foam Protective blocks
- 5. Ear-lite
- 6. Otoscope
- 7. Syringe(s)
- 8. Cuticle or Iris scissors
- 9. Paper Towels
- 10. Earplug storage cases
- 11. Isopropyl or rubbing alcohol
- 12. Dremel tool with burr(s)
- 13. Clear-Seal silicone coating
- 14. Cotton tip applicators
- 15. Dipping cups
- 16. Toothpicks
- 17. Corkboard, sponge, or foam

#### **OPTIONAL ITEMS**

- 1. Identi-Tabs (Red for right)
- 2. Screw-in anchors & cords
- 3. Acoustic Filters
- 4. Tubing
- 5. Core drill
- 6. Tube Threader
- 7. Plunger

#### ALWAYS WASH AND DRY HANDS THOROUGHLY BEFORE YOU BEGIN

## **II INSTRUCTIONS**

#### ONE EXAMINE CLIENT'S EAR

Use otoscope or video otoscope to examine client's ear. To properly inspect the ear, grasp the pinna between your thumb and index finger and gently pull back and up. This will straighten the canal and facilitate the placement of the otoscope in the canal

If there are any indications of excessive (dried) earwax, irregularities in the canal caused by surgery or congential abnormalities, reports of recent surgery to the ear, discharge, or any other contraindications, have client seek medical source for clearance before proceeding. Check the size and direction of ear canal. This is essential to using the correct sized cotton or foam block and comfortably and properly placing the block in the client's ear.

#### TWO INSERTION OF PROTECTION FOAM BLOCK

You must place an appropriately sized cotton or foam block to ensure the safety of your client's ears and to achieve the precision fit offered by The Insta-Mold<sup>®</sup> Process. An otoblock will confine the flow of silicone and help the silicone expand and fill the entire diameter of the ear canal properly.

Using an ear-lite as a guide, insert the otoblock past the second bend of the ear canal. Then, you can cut off a portion of the ear canal during the finishing process and be assured that there will still be enough canal length to achieve an adequate seal.

#### THREE MEASURING & MIXING INSTA-MOLD FEATHERWEIGHT SILICONES

#### INSTA-MOLD TIPS FOR BEST RESULTS:

- 1. Insta-Mold FEATHERWEIGHT silicones are temperature dependent. Use this to your advantage. If you want extra working time, store the material in a cooler location (not below 60° F). If you want to quicken the cure, then warm the material in your hands before and/or after the kneading process, but before placing into the syringe.
- 2. MATCHING BATCH NUMBERS: Always make sure that Part 'A' and Part 'B' Featherweight silicones have matching batch numbers. Whenever Featherweight silicones are ordered, you will always receive matching 'A' and 'B' batch numbers. We cannot guarantee results unless you follow this guideline.
- 3. CONTAMINATION: It is extremely important to keep the Featherweight silicone away from certain contaminants before and during the curing process. These include but are not limited to, the following: Sulfur groups (latex gloves contain sulfur, **DO NOT USE LATEX GLOVES**), Amine groups (including ammonia), alcohols, and other types of silicone catalysts. Be wary of other hand creams, hand lotions (other than our Hand Lotion), and soaps due to the multitude of ingredients they possess. **Only use the Hand Lotion provided in your Insta**-

**Mold kit**. If you are not sure or you want more specific information on possible contaminants, please feel free to call or email our office.

#### MEASURING

With every order of Insta-Mold Featherweight silicones, you will receive two (2) sets of measuring spoons. Each set consists of a ½ tsp., ¼ tsp., and 1/8 tsp. for use with appropriately sized ears. The white spoons are marked 'A' for use with Featherweight part 'A' (catalyst side) and the other set of spoons is marked 'B' for use with the colored Featherweight part 'B.'

# Be sure not to contaminate Insta-Mold Featherweight 'A' with 'B.' DO NOT intermix spoons.

Insta-Mold Featherweight part 'A' and 'B' silicones are mixed in equal amounts or a one to one ratio.

Lightly lubricate fingertips with a few drops of our Hand Lotion. DO NOT USE TOO MUCH. Rub lotion into fingertips. Do not pour lotion into bowl of spoon. Use oily finger to lubricate the bowl of the chosen measuring spoons (A & B). Fill desired scoop 'B' with a level amount of Featherweight 'B.' To avoid cross contamination, wipe excess silicone off hand before measuring part 'A.' Using same size spoon, repeat above procedure for part 'A.' Remove both sides from scoops and place in your hand.

Reminder: Part 'A' will always be the white side and Part 'B' will be your color choice.

As a beginner, it is advisable to use a  $\frac{1}{2}$  teaspoon of each side until you learn to correctly estimate the quantity needed for various ear sizes.

#### MIXING THE SILICONE MATERIAL

Combine equal parts 'A; and 'B' in your hand and knead the materials with your fingers by folding and stretching them until a uniform color and consistent texture is achieved. Usually 30 to 35 kneads in about 30-35 seconds is sufficient.

There is no need to rush. Insta-Mold Featherweight silicones are formulated to give you approximately 2 minutes of working time.

#### SLOWING FEATHERWEIGHT CURE SPEED

While the Featherweight silicone is formulated to give enough working time under normal conditions, sometimes you may need extra working time to mix and syringe the silicone properly. This usually occurs when the temperature is higher than usual (Ex: when working outside on a hot summer day).

Insta-Mold "Cure Inhibitor" can slow down the cure speed and allow more working time during the mixing of the Featherweight silicone mixture.

Simply add and mix one or two drops of "Cure Inhibitor" to either part 'A' or 'B.' Then simply mix with equal parts of its complementary part 'A' or 'B.' It is not advisable to use more than two drops of "Cure Inhibitor" as it may slow the cure too much,.

#### FOUR SYRINGING THE SILICONE INTO EAR

Before continuing, it is imperative to carefully place an appropriately sized otoblock in the ear canal to confine the flow of silicone material. (See step #3) If you have not, STOP, and return to step #3 before proceeding.

While any silicone syringe is acceptable, Insta-Mold recommends its deluxe syringe (part #7014). This syringe allows for easier injecting and offers less waste.

Place mixed silicone material into the barrel of a silicone syringe.

Make sure the collar is at tip of the plunger.

Insert the plunger in the barrel and depress so that the collar is flush with the end of the barrel.

Depress the plunger until the Insta-Mold silicone is at the tip of the syringe. Place the tip of the syringe in the ear canal up against the otoblock. Inject with an easy, steady pressure; slowly withdrawing the syringe as the ear canal fills.

Make sure to keep the tip of the syringe buried in the silicone throughout the entire syringing process. Otherwise, voids and gaps in the mold may result. The remaining material is used to fill the helix and Concha (bowl area). Unlike ordinary impression techniques, do not overfill. For a professional looking earmold, it is important to minimize the amount of material used on the outside of the ear and keep the mold flush or even. This will also make for easier modifying and finishing of the mold later.

Now is the time to decide what type of mold you want. Whether you want a full shell up into the anti helix, half shell, or just a canal mold; only fill the outside of the ear with as much or little silicone as necessary.

Encourage your client to talk and smile. Also, if the client wears glasses and/or dentures, these should be worn while the impression is being taken.

In order to decrease the chance of feedback from TMJ movement, once the silicone material is in the ear, instruct the client to open his/her mouth wide, smile and move his/her jaw side-to-side.

#### FIVE MOLDING & SHAPING IN THE EAR

While the putty is still soft, the outer surface of the earmold is molded to the desired shape, firmed down lightly and smoothed with your finger to give the exterior surface a finished look. To improve the smoothing process, place of drop of Insta-Mold Hand Lotion on your fingertip and continue smoothing with gentle pressure. Apply a little extra lotion to your fingers if necessary. Follow the same procedure to fit opposite ear.

#### Be sure to minimize Hand Lotion use if you are going to insert Identi-Tabs (step #7) or Anchors & Cords (step #8).

#### SIX IDENTI-TAB INSERTION (Optional)

To better identify the left and right ear protector, Insta-Mold offers red circular discs called **"Identi-Tabs**." These discs appear on the outside of the ear protector. Their use permits easier identification of each ear protector in addition to improving the ability to police their use, especially in industry.

Identi-Tabs are simple to use. After you have smoothed out your ear impression, depress the red (right ear) Identi-Tab in the outer surface of the earplug before it starts to cure. **Do not smooth earplug with Hand Lotion until after Identi-tab placement.** Be certain the outside surface of the Identi-Tab is level or below the outside surface of the ear protector. Use an ear-lite, to press the Identi-Tab below the outside surface of the ear protector.

Coating the outside surface of the ear protector with Clear-Seal silicone coating (step #12) will further secure the position of each Identi-Tab.

#### SEVEN REMOVING THE CURED EAR PLUG

For best results, leave silicone in the ear as long as possible. This will allow for increased physical properties, less chance of breakage and greater memory.

At room temperature, the mold should be ready to be removed from the ear in six to seven minutes.

To avoid stress to the ear, first break the seal by pulling the pinna in various directions and also rolling your finger or thumb behind the pinna in the inferior area. Ask the subject to open their mouth. Remove the impression slowly, in a direction consistent with the pre-impression inspection. Try to use a firm, steady pull, not a jerky motion. inspect the canal with an otoscope after removal to be sure the ear is clear

Critically evaluate all areas of the impression for accuracy. Make sure there are no voids or gaps.

#### EIGHT TRIMMING, SHAPING, AND MODIFYING THE MOLD

After removal from the ear, the mold is then trimmed of excess material around the edges of the mold with cuticle or iris scissors. If the otoblock remains attached to the mold at the canal end, it can be removed by cutting a cross section with a razor blade. If the impression does include the second bend, cut the canal just short of the second bend.

The end of the canal, rough, and/or sharp edges may be smoothed or rounded using a dremel or similar tools with sand paper, stone, or metal burrs. Insta-Mold does NOT recommend trying to smooth any other imperfections that come in contact with the inside of the ear. This would eliminate one of the greatest advantages of The Insta-Mold<sup>®</sup> Process, THE TISSUE-TO-TISSUE FIT.

Clean off any earwax, which may have adhered to the earmold, with a paper towel or cotton swab and isopropyl or rubbing alcohol.

If you are making a swim plug or noise protector, now is a good time to instruct the client on inserting and removing his/her molds and to review use & care instructions. If you are going to apply the Insta-Mold Clear-Seal clear coating, be sure to go over these steps now. Once the coating is applied, the molds should not be worn for at least 6 hours.

# For Swimmolds and Noise Protectors proceed to step #11 for optional Clear-Seal application or Step #14 for earmold delivery.

For Further instruction on BTE, acoustic filter or two-way radio preparation follow steps ten (drilling out hole for earmolds) and twelve (insert tubing).

#### NINE DRILL OUT HOLE FOR EAR MOLDS

#### DRILL OUT HOLE - CANAL SIDE

Using core drill (item #7022), drill a hole at canal portion of earmold about <sup>1</sup>/<sub>4</sub> inches deep. Be sure to use a twisting or spinning motion while using the core drill. The canal portion is held straight with fingers to keep the hole centered while drilling. Twist and turn the core drill at least 10 times for a clean cut hole.

#### DRILL OUT HOLE- CONCHA AREA

Using the core drill bore into the Concha. Pick your spot carefully and core out the hole on line to make sure you meet up with the hole drilled from the canal end. Be sure to hold canal straight with fingers.

Once again, to acquire a clean cut hole you should turn or twist the core drill at least 10 times.

If you are going to apply Insta-Mold Clear-Seal silicone coating, it should be applied before earmold tubing is inserted. If you are not using Clear-Seal, go immediately to step thirteen.

#### TEN APPLYING INSTA-MOLD CLEAR-SEAL SILICONE COATING

After applying Clear-Seal, the earmold CANNOT be worn for at least six hours. So before applying, check earmold in client's ear for proper fit, comfort, and absence of acoustic feedback. Also, now is a good time to instruct the client on insertion and removal of his molds and to take the time to review use & care instructions. If everything appears satisfactory, begin the coating process.

Insta-Mold's Clear-Seal silicone coating is the perfect finishing step for your earmolds or ear protectors. Not only does Clear-Seal give your molds a smooth, professional, and polished look, it also helps keep them clean, last longer, and can even be used to repair cracks or separations. In addition, Clear-Seal can be used to tighten or retighten your molds for more protection against water, noise, and acoustic feedback.

Before applying Clear-Seal, clean off excess body oils, earwax, and Hand Lotion from earmold with alcohol. Allow the molds to dry. Featherweight Instant Silicones must be fully cured before applying Clear-Seal. If Featherweight mold still feels slightly tacky, it is not ready.

After opening Clear-Seal, if coating seems jelled, just puncture top layer with cotton tip applicator and the material below should be liquid and ready to use.

To hold earmold or ear protector while coating, insert a toothpick or needle in an inconspicuous area such as the end of the canal or if there is an anchor you can insert the toothpick at its entry point into the mold. Hold the toothpick with mold in one hand and paint mold with Clear-Seal using cotton swab. Remember – after applying Clear-Seal, you will have a tighter seal. If an even tighter seal is desired or necessary, further build up of the earmold can be achieved by applying as many additional coats as desired waiting 3-5 minute intervals. Clear-Seal will also help fill in any marks due to earwax or hairs.

When coating many molds in a short period of time, you may dip your molds instead of painting them. Simply obtain a polypropylene or other chemical resistant cup to hold sufficient Clear-Seal for coating. With toothpick or needle inserted in mold, briefly submerge entire mold into Clear-Seal. After pulling the mold out, be sure to allow excess coating to drip back into cup. Rotate mold several time to allow Clear-Seal to spread out evenly on the mold. Use a cotton swab to wipe off any droplets that may form.

**Do not pour excess Clear-Seal back into the bottle.** Clear-Seal is a moisture cure material and you will be pouring excess moisture back into the bottle as well. This may cause remaining Clear-Seal to prematurely cure in the bottle.

#### REPAIRING CRACKS AND SEPARATIONS WITH CLEAR-SEAL

Cracks, separations and even cuts can be easily repaired with Clear-Seal. First, clean the area of the crack or separation with alcohol. Apply Clear-Seal liberally with a small cotton swab in the center of the split; then, wait one minute for solvent to begin evaporating and press the mold so that the sides of the split come together. Continue to hold in this position for approximately 3-4 minutes to create a seal that will "weld" sides of split together. Then apply Clear-Seal over the entire mold. The repair will be welded securely in several hours, but will not be fully cured for 24 hours. It is important no to test or tamper with the repair during this curing period.

If an anchor gets pulled out of a mold, Clear-Seal can be used to reattach it. Apply Insta-Seal liberally with Q-tip into anchor hole and on the anchor itself. Wait about 1-2 minutes for Clear-Seal to begin curing, thicken, and then reinsert anchor. Once again, full adhesion will not occur for 24 hours.

NOTE: Clear-Seal can be used to repair almost any type damage that can occur to an earmold or ear protector and can also be used to build-up loose fitting molds. Therefore, in most cases, you will be able to repair instead of replace and realize a savings in time and money while improving patient satisfaction.

#### **ELEVEN** DRYING

Stick toothpick with coated mold into corkboard, sponge, or polyurethane foam to let dry for at least ten minutes.

The ear protector for water or noise is now finished. Remind client that he CANNOT wear the mold for at least another six hours. If you offer your patients an Insta-Mold pouch, instruct the patient to remove the molds from the pouch when they get home so they may air out completely.

Further coats can be applied at a later date. Simply wipe mold clean with alcohol and allow alcohol to dry before repeating above procedures.

#### After completing all of the above procedures, be sure to wash hands.

#### TWELVE EARMOLD TUBING INSERTION

Allow earmold to cure for a sufficient period of time before inserting tubing. The earmold must be cured to a firm enough state. If the earmold is not sufficiently cured and the tubing is pulled through too soon, the cured hole will expand and not constrict to tightly hold the "Lock" tubing in place.

Thread tapered end of "Lock" tubing into tube threader. Push tube threader into concha area of bored old of earmold until collared portion (lock) is inside body of earmold. Remove the tube threader when tubing is positioned as desired.

After correct placement, the tapered end of the tubing is cut off.

Alternatively, you can push the tube threader through the earmold from the canal portion through to the outside. Insert the tapered end of the "Lock" preformed tubing into the opening of the tube threader and pull the tubing through the earmold until the collared portion is inside body of earmold. Once again, after correct placement, the tapered end of the tubing is cut off.

#### THIRTEEN INSERT SCREW-IN ANCHORS AND CORDS

Simply pick a spot on the outside of the earplug and screw the blue screw into the left earplug and the red screw into the right earplug. Insert the cord into the hole from the back of the ear, loop it around, insert the cord into the hole a second time, and then pull tight.

If you are using the shoelace style cord, you may need to cut off one half to two thirds of the plastic portion so it is not too long after it is inserted.

When you apply the Clear-Seal as described in section 10, insert toothpick into the same position that you plan to insert the screw-in cord. This will work as a starter hole. **After completing all of the above procedures, be sure to wash hands.** 

#### FOURTEEN PRODUCT DELIVERY

# CLIENT IS NOT TO WEAR FINISHED PRODUCT FOR AT LEAST 6 HOURS AFTER APPLICATION OF CLEAR-SEAL.

If you have not applied Clear-Seal, you may instruct client on insertion and removal of his molds and take the time to review use & care instructions before releasing the client. If Clear-Seal is applied, be sure to go over these instructions before it is applied.

## **III. ADVANCED TECHNIQUES**

#### **ONE MULTI-COLORED OR SWIRLED MOLDS**

Insta-Mold instant silicones are available in a variety of neon colors and skin tones. Not only can you offer different colored plugs, but just like laboratories, the Insta-Mold Process allows you to make multi-color or swirled plugs as well.

The key to this process is to properly mix each Featherweight part 'B' color with part 'A' separately before adding another color.

#### EXAMPLE:

#### For a blue and yellow swirled earplug:

- A) You must be able to work faster when making multi-colored plugs or the first color mixed may cure prematurely. To help alleviate that problem, measure out all of your silicone first, both part A's, and in this example, the yellow, and the blue.
- B) Mix equal parts blue with its part A (matching batch #'s)
- C) After the blue is thoroughly mixed, quickly mix equal parts yellow with its matching part 'A.'
- D) After the yellow is mixed thoroughly, twist or braid both colors together into long cones. The more you twist the silicones together, the more distinct designs you will achieve.
- E) Insert into syringe as specified in step #5 and insert into ear canal. Fill the ear canal as previously directed. When filling the helix and concha, do not move the syringe up and down a lot. Move the syringe immediately up to the helix, fill, and then move back down to the concha. Keep the syringe stationary at the concha and allow the multi-colored silicone to naturally radiate out in all directions.

While this procedure takes a little more practice and skill, the results can be very fun and exciting for both you and your clientele.

#### **TWO** ACOUSTIC FILTERS

When noise levels are not as severe, better communication is necessary or the ability to hear is a safety concern, Insta-Mold® noise protectors can be fit with special acoustic filters. A fixed amount of sound is allowed to travel through these special filters, lowering the noise reduction rating, (NRR-19 dB).

#### INSERTION INSTRUCTIONS

First, drill out a hole in the ear protector by following the same procedure as in STEP #10 – DRILL OUT HOLE FOR EARMOLDS.

The acoustic filter has two holes; the larger entry hole and the smaller exit hole. Place the filter into pre-bent earmold tubing exit hole first until the entry hole is flush with the outside of the tubing.

Insert tubing into earmold hole as in STEP #13 - INSERT TUBING INTO EARMOLD. Pull tubing through outside of the earmold until end of tubing and filter are just below the surface of the earmold. After correct placement, the residual tapered end of the tubing is cut off.

#### THREE RADIO HOOK UP

Connect Insta-Mold earplugs directly to your two-way radio system. Turn down the radio volume and hear radio communications even clearer with continuous protection from dangerous environmental noise.

#### INSERTION INSTRUCTIONS

Once again, drill out a hole in the ear protector by following the same procedure as in STEP #10 - DRILL OUT HOLE FOR EARMOLDS..

Insert tubing into earmold hole as in STEP #13 - INSERT TUBING INTO EARMOLD. Pull preformed tubing through outside of the earmold until there is tubing sticking out both the canal end and front end of ear mold. Connect the preformed tubing that is already sticking out of the front end to the elbow joint of the coiled tubing.

#### IV. INSTA-MOLD FEATHERWEIGHT TROUBLE SHOOTING CHART

- PROBLEM: Featherweight silicone does not cure into a solid rubber mold. It remains soft in the client's ear.
- CAUSE: With Featherweight Instant Silicones, ALWAYS use matching batch numbers for Part 'A' and Part 'B.' NEVER use mismatching batch numbers. Contamination of the silicone stopped the curing process. Be sure to read section #4, part #3 on possible contaminants.
- SOLUTION: Be sure to mix Featherweight Instant Silicones in a one to one ratio with matching batch numbers. To increase the rate of cure of the Featherweight silicone, apply heat before inserting into the syringe. Be sure to avoid contaminants that may inhibit curing.
- PROBLEM: Finished product cracks or separates.
- CAUSE: Kneading/mixing took too long and material began curing before silicone was syringed into the ear. Tip of the syringe was NOT buried in the silicone material during the entire syringing process. This lead to a gap or hairline fracture in the mold.
- SOLUTION: Cut down on excessive kneading time (don't go beyond 45-50 seconds). Keep Featherweight silicones in a cool location. When it gets warm, it will cure faster with less working time. Make sure to use proper technique when syringing the Featherweight silicone into the ear canal.
- PROBLEM: Canal portion of the mold is blunt and does not penetrate canal portion of ear.
- CAUSE: Syringe was not placed deep enough into ear canal or not enough pressure was used during syringing process.
- SOLUTION: Make sure syringe is placed deep enough in the ear canal and enough pressure is used to penetrate to the second directional bend of the ear canal. This is especially necessary when the client has very narrow ear canals or there is a more severe bend. Be sure to use an appropriately sized otoblock before taking the impression.

- **PROBLEM:** Client complains that earmold is loose and the seal is not adequate.
- CAUSE: Silicone was not syringed down to the otoblock properly. For maximum seal, the silicone must get pushed up against the otoblock while syringing so it will expand and fill the entire diameter of the ear canal. Client did not change canal shape during curing cycle by smiling or opening mouth. Client has irregular ear to fit.
- SOLUTION: Coat or recoat with the Clear-Seal silicone coating. You can add as many additional coats as desired or necessary at 5-6 minute intervals. If mold still remains loose, make another earmold.
- PROBLEM: Impression penetrates canal too deeply.
- CAUSE: Silicone was syringed too deeply because no otoblock was used, the wrong size otoblock was used or the otoblock was not inserted correctly.
- SOLUTION: Cut off a small cross section of the ear canal portion with scissors or razor blade. You can smooth edge with the tools mentioned in section #10 and finish with Clear-Seal silicone coating. **Remember: the use of an appropriately placed and sized otoblock is imperative before taking any impression.**

Insta-Mold Products, Inc., its affiliates, and distributors assume no liability for any intended or unintended misuse of this product. It is the customer's responsibility to follow any state and local laws related to the use of this product.

This product is for use by certified health professionals or properly trained individuals only.