Earlens Sitting Hybrid Impression Procedure System

1. Introduction

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

Rx ONLY

2. Earlens Hybrid Impression Procedure and System Description

Instruments and materials:

- Impression Return Box w/ Label
- Topical Light Mineral Oil (OIL02)
- Impression Dispensers (IDG01 only)
- Medial Impression Material Cartridge (blue, low viscosity material)
- Medial Impression Mixing Tip
- Lateral Impression Material Cartridge (pink, high viscosity material)
- Lateral Impression Mixing Tip

Additional standard otological office supplies are required, which include:

- Ear Specula: multiple sizes
- Wax curette
- Triangular tipped metal cotton applicator
- Small suction tips (recommend 5 Gauge, 3 Gauge, and 20 Gauge)
- Thin curved elevator
- Spatula
- Gauze pads: 4x4
- Cotton balls
- EPA registered hospital disinfectant wipes
- Tray (small disposable dish for holding mineral oil)

3. Precautions

Before using the Earlens Sitting Hybrid Impression Procedure and System, read and make sure you understand each of the following safety precautions.

- It is important that the physician use the specified impression materials in the proper sequence when performing this deep impression, and that the instructions are followed. No substitutions for materials in the impression system are allowed.
- The impression procedure should be performed by a physician with relevant experience, such as an ENT or Otologist.
- When using any instruments in the ear canal and particularly when the mixing tip is submerged, be careful to avoid damaging the ear canal or tympanic membrane.
- Do not perform the impression procedure if the Impression Dispenser or any other component appears to be damaged or expired.
- Do not use the lateral impression material in the medial section of the ear canal. This material is not indicated for use in deep canal impressions and should be used exclusively in the lateral section of the ear.

4. Indication for Use

The Earlens Sitting Hybrid Impression Procedure and System is intended for use in individuals 18 years and older to generate an ear canal impression.

5. Contraindications

- Perforated tympanic membrane
- Otitis externa
- Visible hematoma, bleeding or effusion
- Hypersensitivity to contact resulting in bleeding or hematoma at the discretion of the physician
- Bony exostosis, atresia, or excessively restrictive anatomy that would cause difficulty removing the impression material or inability to view the tympanic membrane at the discretion of the physician

6. Clinical Study Results

6.1. Study Overview

Earlens conducted an impression study to collect ear impressions from many different ear canal anatomies and to gain experience with the deep canal impression procedure itself.

6.2 Study Demographics

A total of 78 subjects had bilateral ear canal impressions taken (37 female, 41 male). The total number of ears that had impressions taken was 154 (2 subjects had unilateral impressions). Subject age ranged from 32 to 82 years with an average of 66.1 years. The subjects were seen across three clinical sites.

6.3 Outcomes

Number of Impressions

A total of 200 ear impressions were taken on 154 ears (78 subjects). Fourteen subjects (18%) required more than one clinic visit to obtain adequate ear impressions. Multiple impressions were required on some subject ears due to the presence of voids in the impression of anatomical areas that are critical to the custom-build of the Tympanic Lens. The average number of impressions per subject was 2.6, or 1.3 per ear. Thirty-eight percent of subjects required three or more impressions; 17% required four or more impressions.

Comfort During Procedure

Based on a subject survey, a total of 84% of impressions were rated as either no discomfort or mild discomfort.

Ear Canal Status

While 80% of the study ears were observed to be normal (unremarkable otoscopic inspection) after the impression procedure, the remaining ears were reported with minor skin contact findings. The most common observation was a micro-hematoma (16%) while petechia (1%), ecchymosis (2%) and abrasion (1%) was reported less frequently. All otologic findings resolved without treatment and without sequelae. Micro-hematomae and ecchymoses can take 2-4 weeks to resolve. Abrasion and petechia, depending on extent and location, can be a more minor finding and may or may not require delay of subsequent otologic procedures, including Tympanic Lens placement.

7. Operating Instructions

1. Provide an overview to the patient about the impression process and what to expect, including:
    - The ear will be inspected for any contraindications.
    - The ear will be cleaned, any wax or skin debris present will be removed and the ear canal will be lubricated with mineral oil. From the cleaning procedure there may be sensations such as a cough reflex, tickle, or general discomfort.
    - The ear canal and conchal bowl will be filled with impression material. The patient should remain still and try and hold their mouth closed in a resting position without clenching teeth. The patient should avoid talking while the impression material is curing in the ear.

        - The patient may feel a sensation of fullness when the impression material is being applied to the ear canal.
    - The patient will be in both the supine and seated position during the procedure.
    - In a supine position the medial “blue” material is inserted into the medial ear canal. After eight minutes, the medial impression material will set-up and cure. During this time, the sensation of hearing may be diminished due to the presence of the impression material in the ear canal.
    - After the medial impression, the patient will be asked to move to a seated position and lateral (pink) impression material will be inserted into the ear canal. This material will cure over three minutes. It is important that the patient doesn’t talk or otherwise move their jaw during this curing time.
    - The impression is then removed. This may cause a sensation of pressure or discomfort. There is a possibility of discomfort, bruising, abrasion and/or minor bleeding of the ear canal during this procedure.
2. Perform an otologic exam and inspect the external auditory canal and the tympanic membrane for the presence of any contraindications.
    - Do not proceed with the impression procedure if any of the contraindications are present.
3. Clean cerumen and epithelial debris from the ear canal, anterior sulcus, and tympanic membrane. Use a cotton wisp and the provided mineral oil.
    - Do not use any water based cleaning fluids.
    - Do not proceed with the impression if bleeding or if a hematoma occurs as a result of the cleaning process.
4. Wipe out the ear canal, TM and anterior sulcus with a clean cotton wisp to remove any excess oil. Repeat with a new cotton wisp until it comes out dry.
    - Avoid excessive pooling of mineral oil, which may cause defects in the quality of the impression.
5. Prepare the Impression Dispensers, Impression Material Cartridges, and Mixing Tips for dispensing:
    - Test the actuation of both Impression Dispensers, ensuring that the handles smoothly ratchet the piston forward. Do not use an Impression Dispenser if it appears to be damaged.
    - Load the Medial Impression Material Cartridge into one Impression Dispenser. The lower viscosity, blue, medial impression material is intended to be put deep in the ear canal and in contact with the tympanic membrane.
    - Load the Lateral Impression Material Cartridge into the other Impression Dispenser. The higher viscosity pink, lateral impression material is intended to be deposited lateral to the medial impression in the outer ear canal.

      IMPORTANT: Do not use the lateral impression material in the medial section of the ear canal. This material is not indicated for use in deep canal impressions and should be used exclusively in the lateral section of the ear and is NOT intended to be in direct contact with the tympanic membrane.

    - Remove the caps from the impression cartridges.
    - Prior to attaching the Mixing Tip, prime the Medial Impression Cartridge by dispensing a small amount of medial impression material onto a piece of gauze or an equivalent, then wiping any excess material off of the end of the cartridge. Confirm that both materials (blue and white) are advancing equally from the tip.

      IMPORTANT: Ensure there is not mixing of the two materials (blue and white) between the outlets of the cartridge after wiping.

    - Prior to attaching the Mixing Tip, prime the Lateral Impression Cartridge by dispensing a small amount of medial impression material onto a piece of gauze or an equivalent, then wiping any excess material off of the end of the cartridge.

      IMPORTANT: Ensure there is not mixing of the two materials (pink and white) between the outlets of the cartridge after wiping.

- Attach the single use Mixing Tips to the respective impression material cartridges. Orient the curved tip on the Medial Impression Mixing Tip for the right or left ear.
  Note: It is important not to move or rotate the Medial Mixing Tip around the Medial Impression Material Cartridge once attached.

6. First position the patient in the supine position. Then position the patient's head for making the impression, being sure that there is an adequate view of the tympanic membrane, and dispense the medial (blue) impression material into the ear:
   - With the speculum in place, place the distal end of the mixing tip between the umbo and the inferior anterior annular area.
   - Start a timer. Slowly dispense the impression material into the anterior sulcus and onto the tympanic membrane.
     Note: It is important not to move the tip of the dispenser until the tympanic membrane is fully covered keeping the Mixing Tip submerged. Too rapid of a flow may trap air in the anterior inferior sulcus and in the pars flaccida area, which will yield an incomplete impression. As a guide, allow approximately 10-15 seconds to fully cover the tympanic membrane, dispensing material at a slow and steady pace.
   - Once the tympanic membrane and pars flaccida are covered with the impression material, slowly withdraw the tip laterally, keeping the tip slightly submerged and proceed to more rapidly fill the external auditory canal up to a level slightly medial of smooth skin/glandular skin transition on the anterior / superior aspect of the canal. The medial impression material should not be filled beyond the smooth skin/glandular transition.
   - Stop dispensing the medial impression material.
   - Allow the medial impression material to cure for a **minimum of eight minutes** after the completion of the medial impression. The patient should remain still and hold the mouth closed in a resting position without clenching teeth. The patient should avoid talking while the impression material is curing in the ear.
7. Reposition the subject to a sitting position with head and back as vertical as possible and begin the lateral impression. The patient should remain still, with head facing forward, and hold the mouth closed in a resting position without clenching teeth.
   - Purge the air from the Lateral Impression Material Cartridge by squeezing the handle until a small amount of the impression material exits the end of the cartridge. Wipe the tip clean.
   - Attach the Mixing Tip.
   - Position the Lateral Mixing Tip into the canal against the existing medial impression material. The distal end of the Lateral Mixing Tip should be directed towards the superior aspect of the existing medial impression material (blue) that was previously dispensed into the ear canal.
   - While dispensing the lateral impression material, ensure the distal end of the Mixing Tip remains buried in the lateral impression material as the remaining aspects of the canal are filled. Slowly withdraw the tip laterally as the canal is filled and maintain a consistent dispensing speed.
   - Once you have completely filled the canal, advance the material in a clockwise direction for the right ear and counterclockwise direction for the left, filling the concha bowl first. Fill the canal and concha bowl with the Lateral Impression Material (pink) to the level of the scapha, covering the tragus and filling the concha cymba.
     - Optionally, create a pile of the impression material that protrudes laterally from the concha bowl for ease of impression removal.

- Allow the lateral impression material to cure for a **minimum of three minutes** in the sitting position. The patient should remain still, with head facing forward, and try and hold the mouth closed in a resting position without clenching teeth. The patient should avoid talking while the impression material is curing in the ear.

8. Reset the Impression Dispensers by depressing the lever on the back of the piston and pulling proximally, detach the Impression Material Cartridge and Mixing Tip from each Impression Dispenser.
   - Discard the single-use Mixing Tips, and discard the Impression Material Cartridges, if desired. It is acceptable to save the impression material cartridges for use in another impression if there is adequate unused material left.

     Note: The Impression Dispenser has a useful life of 300 patients.
9. With the subject in an upright sitting position remove the fully cured impression. Loosen the impression from the conchal skin and external auditory canal and break the seal between the impression material and the ear canal wall. Carefully remove the cured impression material from the ear.
   - Ask the patient to open and close their jaw as if they are trying to “pop” their ears
   - While grasping the impression and pulling the pinna posteriorly to straighten the canal, slowly rotate the impression toward the patient’s nose (anterior direction) while gently increasing the amount of pull force applied. Gentle twisting forces may be applied as the impression is slowly removed from the ear canal.
   - Ask the patient to indicate whether they experience a feeling of a pressure drop or an increase in hearing. This is a sign that an air leak path down to the tympanic membrane has been formed.
10. Inspect the ear canal and tympanic membrane.
11. Inspect the impression to see if it is complete and acceptable or requires a repeat attempt. Flaws that may require a repeat attempt include the following (see Figures 1, 2, 3):
    - Inclusion of cerumen or epithelial plaques in the umbo and anterior sulcus areas.
    - Voids, flaws and bubbles in the area of the umbo or anterior sulcus areas indicating an incomplete impression in the tympanic membrane region.
    - Voids, flaws, and bubbles at the transition or junction between the medial and lateral impression material. Also ensure the transition point is not past the smooth skin/glandular skin transition.
    - Voids, flaws, and bubbles indicating an incomplete impression in the ear canal and conchal bowl region. Small bubbles and voids are acceptable in the ear canal and conchal bowl regions.
12. If the impression is unacceptable, repeat the procedure a second time, beginning with Step 4.
    - Do not repeat the procedure if any of the contraindications have developed.
    - Do not exceed two attempts per ear per day.
13. Alternatively, if only the medial aspect of the impression is unacceptable, repeat the deployment of the medial impression material (blue) portion of procedure to obtain a short medial impression:
    - Repeat Step 5 (Dispenser Preparation) for the Medial Impression Material Dispenser.
    - Follow Step 6 to dispense the medial impression material (blue) into the ear up to the level of the anterior bulge, then stop.
    - Allow the impression material to cure for a **minimum of eight minutes**.
    - Gently loosen the impression material using a right angle pick to break the seal between the impression material and the ear canal wall, then carefully remove the cured impression material from the ear with a right angle pick.
    - Repeat Step 10 (Ear Canal Inspection) and Step 11 (Impression Inspection).
    - **Note:**
      - Avoid applying excessive force in the medial direction when loosening and removing the short medial impression.
      - Do not repeat the procedure if any of the contraindications have developed.
      - Do not exceed two attempts per ear per day
14. Repeat all steps for the opposite ear (if necessary).

15. Once all impressions for a single patient are completed, and if impression material is going to be used on a subsequent patient, replace the clean cap on the cartridge. Wipe down the dispenser and impression material cartridge (if re-use is planned) with an EPA registered hospital disinfecting wipe to prevent any possible cross contamination. Dispose of all single-use items.
16. Prepare and send the impression(s) to Earlens by placing all impressions taken in the supplied Impression Return Box and labeling the container with patient identification.

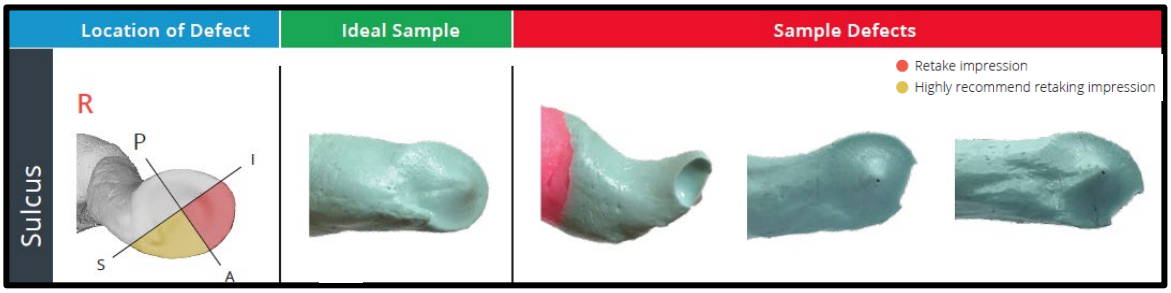

Figure 1: Medial Sulcus Impression Examples – an ideal medial impression features a complete sulcus which is needed to prepare an adequate contact platform for the Lens.

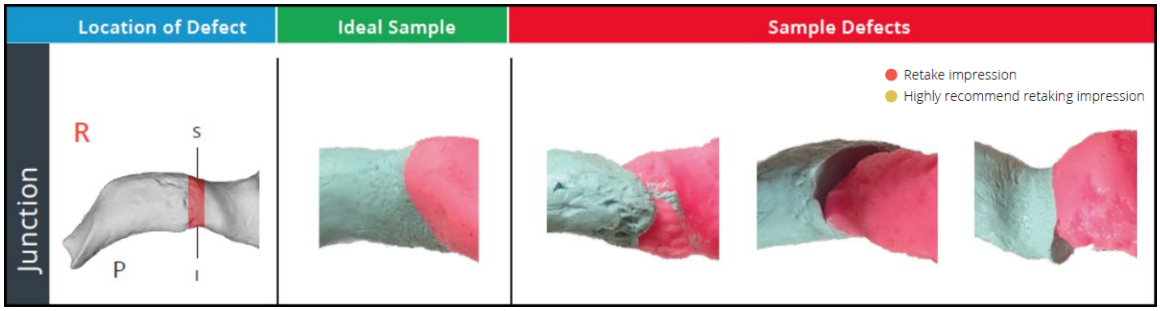

Figure 2: Medial & Lateral Junction Impression Examples – an ideal junction features a smooth transition between the medial and lateral materials with no voids.

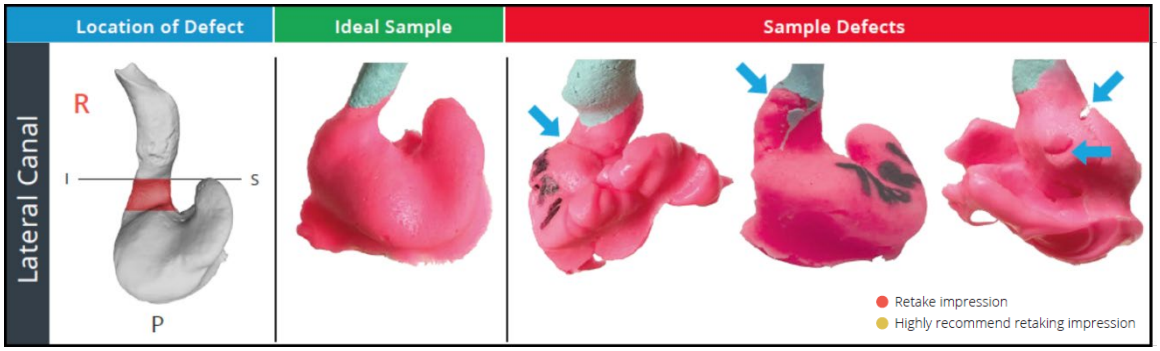

Figure 3: Lateral Impression Examples – an ideal lateral impression has no folds or voids and is smooth.

8. Graphic Symbols Contained in Device Labeling

Symbol	Description	Reference	Symbol	Description	Reference
	Consult instructions for use	ISO 15223-1:2016, 5.4.3		Temperature limit	ISO 15223-1:2016, 5.3.7
	Use-by date	ISO 15223-1:2016, 5.1.4		Caution	ISO 15223-1:2016, 5.4.4
	Batch code	ISO 15223-1:2016, 5.1.5		Catalog number	ISO 15223-1:2016, 5.1.6
	CE conformity marking	MDD 93/42/EEC, Annex XII	RxOnly	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)	FDA Final Rule 81 FR 38911
	Humidity limitation	ISO 15223-1:2016, 5.3.8			

Manufactured by (Ref. ISO 15223-1:2016, 5.1.1):
Earlens Corporation.
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EC REP

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CE