1. **Introduction**  
CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

**RxOnly**

2. **Earlens Impression System Description**

   Instruments and Materials:
   
   The Earlens Impression System includes:
   
   1) Impression Return Container
   2) Impression dispenser (SIK001 Only)
   3) Topical Light Mineral oil (SIK001 Only)
   4) Impression Material Cartridge
   5) Mixing tip
   6) Removal Handle

   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
   - Right angle pick
   - Gauze pads: 4x4
   - Cotton balls
   - EPA registered hospital disinfectant wipes
   - Tray (small disposable dish for holding mineral oil)
3. Precautions

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

1. It is important that the physician use the specified impression material when performing this deep impression, and that the instructions are followed. No substitutions for materials in the impression system are allowed.
2. The impression procedure should be performed by a physician with relevant experience, such as an ENT or Otologist.
3. 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 as tympanic membrane perforation may occur.
4. Do not use the Earlens Impression System if the Impression Dispenser or any other component appears to be damaged.
5. Do not perform the impression procedure under General Anesthesia.
6. Use of local anesthesia during the impression procedure is not recommended.

4. Indication for Use

The Earlens Impression Kit is intended for use in adults to generate an ear canal impression.

5. Contraindications

- An abnormal tympanic membrane (deemed perforated, inflamed or has dimeric or monomeric area, or in any other way abnormal)
- Otitis externa.
- Visible hematoma, bleeding or effusion.
- Hypersensitivity to contact resulting in bleeding or hematoma to 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 to the discretion of the physician.

6. Clinical Study Results

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.
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.
3. Outcomes:
   o 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 transducer. 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.
   o Comfort during procedure: Based on a subject survey, a total of 84% of impressions were rated as either no discomfort or mild discomfort.
   o 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
sequelea. 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 transducer placement.

7. Operating Instructions

1. Explain to the subject:
   - 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 subject should remain still and try and hold their mouth closed, so that teeth are touching without clenching teeth. Subject should avoid talking while the impression material is curing in the ear.
   - The Subject may feel a sensation of fullness when the impression material is being applied to the ear canal.
   - After ten minutes the impression 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.
   - 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. A small amount of the provided mineral oil may be used if needed.
   - 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. If necessary, lubricate the tympanic membrane, ear canal, and conchal bowl with the provided mineral oil.
   - Due to variations in anatomy the amount of oil required may vary. If oil is necessary, cover any surfaces that require lubrication with a thin coating of oil.
   - Inspect the tympanic membrane area to ensure there is no pooling of oil, which may cause defects in the quality of the impression. It may be necessary to aspirate any pools of mineral oil with a small suction tip. A very small wisp of cotton on a triangular-tipped metal cotton applicator can be also used to absorb small pools of oil from the anterior sulcus which frequently is not visible and can harbor unseen residual solution.

5. Prepare the Impression Dispenser, Impression Material Cartridge, Mixing Tip for dispensing:
   - Test the actuation of the Impression Dispenser, ensuring that the handle smoothly ratchets the piston forward. Do not use the Impression System if the Impression Dispenser appears to be damaged.
   - Load the Impression Material Cartridge into the Impression Dispenser.
   - Remove the cap from the impression cartridge.
   - Attach the single use mixing tip to the impression material dispenser with the curved tip oriented for the right or left ear.
   - NOTE: It is important not to move or rotate the Mixing Tip around the Impression Material Cartridge once attached.

6. Position the subject’s head for making the impression, being sure that there is an adequate view of the tympanic membrane, and dispense the impression material into the ear:
   - With the speculum in place, place the distal end of the mixing tip very close to the umbo region of the tympanic membrane.
Slowly dispense the impression material onto the tympanic membrane starting between the umbo and the anterior sulcus. Allow the impression material to run slowly into the anterior, inferior sulcus and continue slowly dispensing until the impression material fully covers the tympanic membrane.

NOTE: It is important not to move the tip of the dispenser until the tympanic membrane is fully covered and the 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. As a guide, allow approximately 60 seconds to fill the ear canal dispensing material at a more rapid and steady pace.

Once the canal is filled, remove the speculum and slowly fill the conchal bowl to the level of the scapha, covering the tragus. Remove the mixing tip from the canal and concha.

If the optional Impression Removal Handle will be used, insert the Impression Removal Handle into the pool of impression material in the conchal bowl, ensuring it protrudes laterally from the ear canal.

Reset the Impression Dispenser by depressing the lever on the back of the piston and pulling proximally. NOTE: The Impression Dispenser has a useful life of 100 patients.

Detach the Impression Material Cartridge and Mixing Tip from the Impression Dispenser. Discard the Impression Material Cartridge and the mixing tip.

7. Allow the impression material to cure (10 minutes total). After three minutes, the material will have cured enough that the subject can be put upright for comfort or left in the supine position as desired.

8. 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.

A small spatula can be used to gently separate the impression from the wall of the lateral external auditory canal.

Ask the subject to indicate whether they experience a feeling of a pressure drop or an increase in hearing which may or may not occur. This is a sign that an air leak path down to the tympanic membrane has been formed.

While grasping the impression and pulling the pinna posteriorally to straighten the canal, slowly rotate the impression and gently wobble it up and down. Ask the subject to open and close their jaw as if they are trying to “pop” their ears. While applying gentle twisting forces and wobbling the impression up and down, continue to gently increase the amount of pull force applied and slowly remove the impression from the ear canal.

9. Inspect the ear canal and tympanic membrane.

10. 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:

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 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).

GOOD IMPRESSION  NOT ACCEPTABLE  NOT ACCEPTABLE
11. If the impression is unacceptable, repeat the procedure a second time, beginning with Step 4 (Lubrication).
   - NOTE: Do not repeat the procedure if any of the contraindications have developed.
   - NOTE: Do not exceed two attempts per ear per day.

12. Alternatively, if only the medial aspect of the impression is unacceptable, repeat the procedure to obtain a short medial impression:
   - Repeat Step 4 (Lubrication) through Step 5 (Dispenser Preparation).
   - Follow Step 6 to dispense the material into the ear up to the level of the anterior bulge, then stop.
   - Allow the impression material to cure (10 minutes total). After three minutes, the material will have cured enough that the subject can be put upright for comfort or left in the supine position as desired.
   - 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 9 (Ear Canal Inspection) and Step 10 (Impression Inspection).
   - NOTE: Avoid applying excessive force in the medial direction when loosening and removing the short medial impression.
   - NOTE: Do not repeat the procedure if any of the contraindications have developed.
   - NOTE: Do not exceed two attempts per ear per day.

13. Repeat all steps for the opposite ear (if necessary).

14. Once all impressions for a single patient are completed, replace the clean cap on cartridge. Wipe down the dispenser and impression material cartridge with an EPA registered hospital disinfecting wipe to prevent any possible cross contamination. Dispose of all single-use items.

15. Prepare and send all the impression(s) to Earlens
   - Rinse the impression clean with IPA; then wipe down with an EPA registered hospital disinfectant wipe.
   - Place the impression in the supplied container and label the container with the subject’s name, right or left ear, and date.
   - Place all right and left ear impression containers in a shipping box with an identifiable label. Ship the impressions to Earlens along with the completed order form.

8. Graphic Symbols Contained in Device Labeling
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Manufactured by (Ref. ISO 15223-1:2012, 5.1.1):
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