

PERFIT Ear Impression Silicone

Instructions for Use

Version: 01

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1. General Description:

The product is a high-performance two-component addition-curing silicone impression material, specially designed for audiology applications.

2. Intended Purpose:

For ear impression taking.

3. Contraindications:

Not suitable for those who are allergic to silicone material.

4. Side Effects:

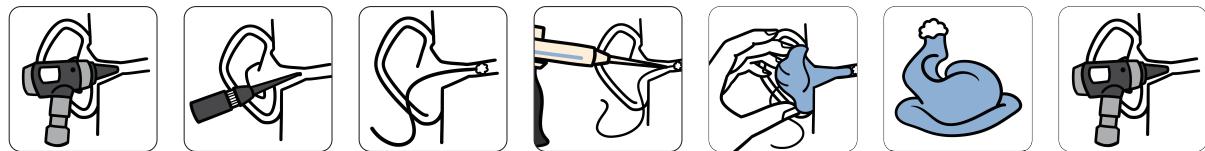
There are currently no known side effects or interactions.

5. Technical parameter:

| Model | Working time | Minimum time in ear | Hardness |
|---------|--------------|---------------------|------------|
| A/RAPID | 30" | 1'30" | 40 Shore A |

Tips: the above mentioned working time refers to that at room temperature (23°C) and normal air humidity (50%). With higher temperature the time can be shorter and with lower temperature the time can be longer

6. Method of Operation:



- ① Examine the ear: To make sure there are no injuries, inflammations and other issues that could affect the operation.
- ② Prepare the ear: Clean and depilate the ear canal.
- ③ Place the impression pad: To control the injection depth and protect the eardrum.
- ④ Apply the impression material: Remove the cap of the cartridge, insert the mixer and load the cartridge into the dispenser. Extrude and discard the first 1–2 cm of material to avoid uneven mixing and air entrapment. Slowly apply the homogeneously mixed material into the ear canal and concha. Please ensure that the tip of the mixer remains inside the material during application to avoid leaving any gaps. After use, leave the mixer as a cap on the cartridge until the next application.
- ⑤ Setting of the material: The material will set into an elastomer after the "Minimum time in ear".
- ⑥ Finish the impression: Gently loosen the cured impression from different angles using fingers, then carefully remove it.
- ⑦ Check the ear: To ensure no material residue!

7. Precautions:

(1) For operation

- Only for trained specialists.
- Addition-cure silicone can be inhibited by several substances, including sulfur-containing materials (e.g. vulcanized rubber, latex gloves), amine compounds (e.g. epoxy hardeners, bonding agents, some disinfectants), tin-based catalysts (from condensation silicones or old molds), incompletely cured composite resins, certain metal ions (e.g. copper, iron, mercury, chromium). Latex gloves are the most common cause of curing problem.
- If it accidentally gets on your clothes, don't wipe it immediately. Wait until it cures. It will be easier to remove.
- We are not responsible for any problems caused by uses other than those specified in the manual.

(2) For storage

- Keep away from children.
- This product should be sealed and stored in a cool, dry place at a temperature between 5–25°C.

Note: Notification of any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in your country.

8. Shelf life:

3 years

9. Accessory:

Mixer

10. Disposal:

Dispose in accordance with local regulations.

11. Symbols for use in the labelling:

 — Temperature limit

 — Manufacturer

 — Caution

 — Use-by date

 — Batch code

 — Consult instructions for use

 — Authorized representative in the European Community

 — Do not re-use

 — Country of manufacture

 — Medical device

 — Unique device identifier

 — Caution: U.S. Federal Law restricts this device to sale by or on the order of a dentist or professionals

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