

# Impression Silicone IS-1.1

## Instructions

pro3dure  
medical

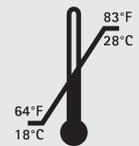
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**Indications for use:**  
Ear impression taking

### Technical data:

- Mixing volume: 50 ml cartridge
- Mixing ratio: 1:1
- Color code: Base: orange Catalyst: white
- Setting time: 3,5 - 4,5 min. at body temperature
- Final hardness: 35 ± 5 Shore A
- Application: At 73 ± 4 °F, 50 ± 5 % rel. humidity
- Storage:



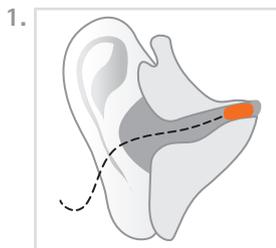
### Ordering information:

**Standard packing:**  
item no.: A0010100  
Cartridges of 8 x 50 ml  
Base and Catalyst

**Static mixers:**  
4,2 mm/yellow/50 pcs.  
item no.: A4020141

**Dispensing gun:**  
S 50  
item no.: A4020139

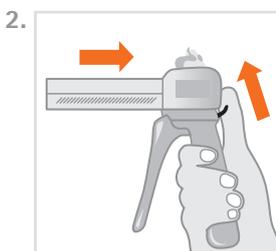
These data result from measurements of a representative sample, which were determined within the scope of our quality assurance.



### 1. Preparation of the ear

The auditory canal and the eardrum have to be examined before taking an impression. Ear impressions shall not be taken if there is any indication of distinctive features found (e.g. perforation or inflammation of the tube or eardrum). The auditory canal has to be cleaned and depilated. In case of insufficient cleaning the curing mechanism of the impression material can be affected (e.g. by cerumen). In addition to cleaning it is recommended to generate a thin separation layer between the impression material and the whole skin contacted area (e.g. auditory meatus, concha and marginal areas of the auricle). In order to achieve that the relevant areas shall be moisturized with a lubricant solution, using a wadding stick or cotton pad. By conditioning the ear in the mentioned way cured impression material is easier to remove and a more homogeneous cured surface of the ear impression (reduced inhibition layer) is gained.

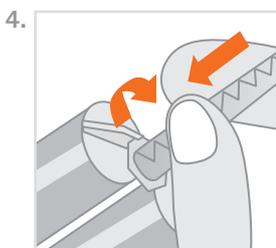
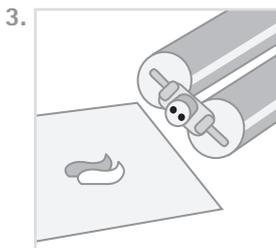
The eardrum must always be protected with an impression plug placed at the end of the external auditory canal in front of it, before taking an impression. The impression silicone IS-1.1 is now dispensed directly into the conditioned ear of the patient as described under point 2.



### 2. Mixing and dispensing

Place the cartridge (fig.2) into the dispensing gun. Unscrew cap. In order to ensure a proper flow and mixing ratio from both orifices (fig.2) extrude carefully a small amount of the material (fig.3). Insert the static mixer into the guided grooves of cartridge. Rotate the mixing cannula anti-clockwise to a stop (fig.4). If necessary, mount an Intra-tip. For reducing forces during dispensing, static mixers of a larger diameter (9mm) can be used alternatively. Dispenser is now ready to mix the 2 component impression silicone in any amount needed. Slowly inject the silicone material into the auditory canal until concha is filled completely (see fig.5).

The special flowing characteristics of pro3dure's impression silicone IS-1.1 allows an almost pressure free, constant flow into the ear. Keep always the end of the static mixer immersed on the surface of the injected material during injection. In order to seal the cartridge leave the static mixer on it after use. After curing remove the ear impression carefully and control the ear again.



### 3. Important working hints

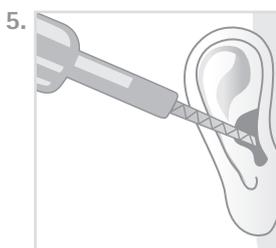
- A careful preparation (point 1.) as well as a thorough cleaning of the auditory canal before taking the impression will ensure better and more reliable results.
- Ensure that all traces of impression material is removed from the patient's ear.
- The cured impression material IS-1.1 is chemically inert. Avoid spots on clothing.
- We recommend standard gloves made of nitrile or polyethylene.

### Safety advice:

The impression taking of the external auditory canal has to be executed by trained specialist staff only. The working instructions and precautions have to be strictly considered. Nonobservance can lead to irreparable damage of the ear or ear drum. pro3dure medical is not liable for any damage caused by improper application of the impression material.

Despite of the fact that the high biocompatibility of silicone materials is proven over decades in exceptional cases undesired reactions of the immune system like allergies, irritations can't be absolutely excluded. In case of doubt, we recommend to contact your consulting physician and make an allergy test before the application of the material.

For use by trained specialists.



IS-1.1

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