IMPRESSION TAKING PROCEDURE

Two-step impression technique (double step impression):



1A



2A



3A



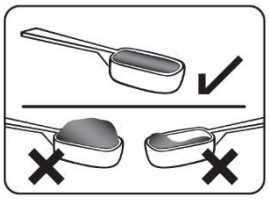
4A



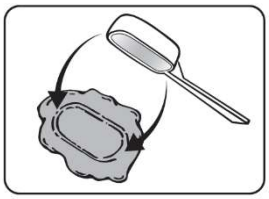
5A

PREPARING THE DEVICES: STEP-BY-STEP INSTRUCTIONS

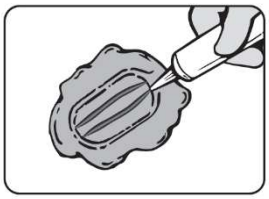
200ml/900ml/25 kg jars (Protesil Putty) – 60 ml tube (Protesil Catalyst Gel)



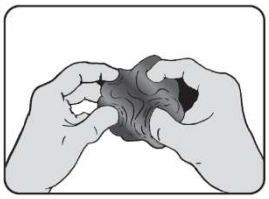
1.1



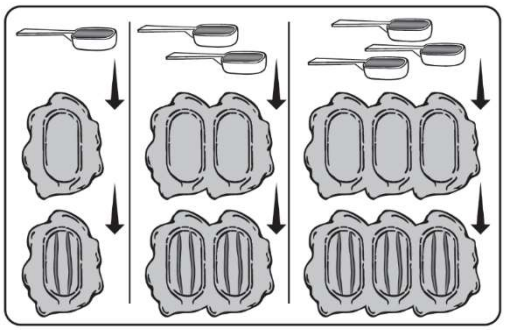
1.2



1.3

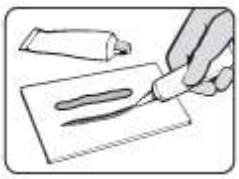


1.4



1B

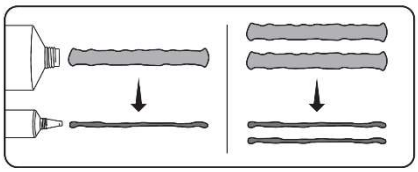
40/140 ml tube (Protesil Light) – 60 ml tube (Protesil Catalyst Gel)



2.1



2.2

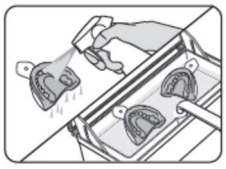


2B

DISINFECTING AND CLEANING THE DEVICE: GENERAL STEP-BY-STEP INSTRUCTIONS



1C



2C

C-silicones

Instructions for use

1. **INTENDED USE**

C-silicone dental impression material

2. **PRODUCT DESCRIPTION**

Protesil Putty: High viscosity condensation polysiloxane (base) recommended for the two-phase technique (double step impression) in combination with Protesil Light fluid.

Protesil Light: Low-viscosity condensation polysiloxane (base) recommended for the two-phase technique (double step impression) in combination with Protesil Putty.

Protesil Catalyst Gel: catalyst for condensation polysiloxanes. To be used for the polymerisation of Protesil Putty and Protesil Light. The Indurent Gel catalyst can be supplied separately from the bases of the materials it is combined with for mixing.

3. **PACKAGING**

200 ml jar of base (Protesil Putty)
900 ml jar of base (Protesil Putty)
25 kg jar of base (Protesil Putty)
40 ml tube of base (Protesil Light)
140 ml tube of base (Protesil Light)
60 ml tube of catalyst (Protesil Catalyst Gel)

4. **COMPOSITION**

Protesil Putty*:* Polysiloxanes (hydroxy terminated), silica fillers, inorganic aluminum fillers, hydrocarbons, pigments, peach flavouring.

Protesil Light: Polysiloxanes (hydroxy terminated), silica fillers, surfactants, pigments.

Protesil Catalyst Gel: Organotin compound, alkoxysilanes, hydrocarbons, pigments, mint flavor.

5. **INSTRUCTIONS FOR USE**

The devices are intended for use in the dental sector by trained and qualified professionals for the purpose of impression taking on dental patients from 3 years of age.

6. **CONTRAINDICATIONS**

Do not use on patients with known hypersensitivity to any of the components. For more information on the allergens present, please contact Vannini Dental Industry.

7. **SIDE EFFECTS**

Irritation, redness or signs of hypersensitivity may occur in case of allergy to any of the components.

8. **CLINICAL BENEFITS**

Impression material for negative reproduction of dental arches for use in diagnosis and treatment.

9. **STEP-BY-STEP INSTRUCTIONS**

9.1 GENERAL PRECAUTIONS/WARNINGS:

The product's instructions for use must be kept for the duration of its use. Use gloves, protective goggles, face mask, and suitable clothing. Use on pregnant women is not recommended. In order to reduce the risk of cross-contamination, always use new, uncontaminated gloves when handling cartridges, tubs, tubes and accessories. Packs should be kept in environments that are free of microbial contamination. Store the product at temperatures of between 5°C / 41°F and 27°C / 80°, and keep away from direct sunlight. Vapours with a characteristic alcohol

odour may be released during mixing; do not inhale. Do not ingest. If ingested, seek immediate medical advice. Safety Data Sheet available subject to request. Dispose of the product responsibly. The product (material, polymerised material and impression) and packaging must be disposed of in compliance with applicable local regulations.

9.2 GENERAL PRECAUTIONS/WARNINGS ON DEVICE PREPARATION:

Do not overfill the impression tray, as this could cause ingestion and trigger the patient's emetic reflex. Dispense the strips of product trying to keep the diameter of the dispensed material the same as the outlet hole on the tube. Observe indicated doses. Incorrect doses may influence the material's dimensional stability and polymerisation times. Do not use after the expiry date indicated on the packaging. Do not use the material if the batch details and expiry date are not indicated on the outer packaging. Do not use the product if the main packaging is damaged. The devices should be used within a professional dental environment (legally-certified public or private health facilities). Use the product at an ambient temperature of 23°C/73°F (higher temperatures reduce working time, lower temperatures extend working time).

9.3 GENERAL PRECAUTIONS/WARNINGS ON THE USE OF THE DEVICE:

Use is not recommended on patients who are sensitive to condensation silicones. If irritation, redness or other signs of hypersensitivity occur, stop using the product and take the steps necessary to ensure the patient's safety. In order to avoid complications, it is advisable to block excessive undercuts before taking the impression. Always check that the material has set completely before removing the impression from the patient's mouth. Once the impression has been taken, check its integrity and make sure there are no material residues in the patient's mouth. When performing the double step impression technique, wash the first impression and dry it thoroughly to improve adhesion between the two viscosities. As silicones leave indelible marks, avoid contact with clothing.

9.4 PRELIMINARY OPERATIONS:

1. Read the instructions for use.
2. Use protective gloves, face mask, protective goggles and suitable clothing.
3. Select the impression tray with retention rims.
4. Then choose the impression technique to be used.

9.5 IMPRESSION TAKING PROCEDURE

Two-phase technique (double step impression):

1. Prepare the **high-viscosity** material device to be used for the first impression.

See paragraph 9.6 for details on how to prepare the device.

2. Mix the **high-viscosity** material, observing the mixing times (see paragraph 10, technical data table).

3. Place a suitable amount of the **high-viscosity** material on the impression tray (fig. 1A).

4. Take the first impression by placing the loaded impression tray inside the patient's mouth within the clinical working time (see paragraph 10, technical data table) (fig. 2A).

5. Remove the impression from the patient's mouth when the setting time has been reached (see paragraph 10, technical data table).

6. Wash the first impression and dry it thoroughly.

7. Process the first impression.

8. Prepare the **low viscosity** material device to be used for the second impression. See paragraph 9.6 for details on how to prepare the device.

9. Mix the **low-viscosity** impression material, observing the mixing times (see paragraph 10, technical data table).

10. Apply a suitable amount of **low-viscosity** material where necessary (preparations, first impression, etc.) (fig. 3A and 4A) and place the reloaded impression tray back inside the patient's mouth to take the second impression within the clinical working time (see paragraph 10, technical data table) (fig. 5A).

11. Remove the impression from the patient's mouth when the setting time has been reached (see paragraph 10, technical data table).

12. Disinfect as shown in paragraphs 9.7 and 9.8.

To avoid compromising the performance of the products, it is essential to respect the timing indicated in the technical data table for each phase.

9.6 PREPARING THE DEVICES

SPECIFIC WARNINGS:

60 ml tube (Protesil Catalyst Gel)

In order to reduce the risk of cross-contamination, always use new, uncontaminated gloves when handling tubes and accessories. Use with Protesil Putty and Protesil Light only. The Protesil Catalyst Gel causes skin irritation. Use gloves, protective goggles, face mask, and suitable clothing. Avoid direct contact between the catalyst and skin and eyes. In the event of accidental contact with the eyes, wash thoroughly with water and seek immediate medical advice. In the event of accidental contact with the skin, wash thoroughly with soap and water. If irritation, redness or other signs of hypersensitivity occur, during the use of Protesil Catalyst Gel, stop using the product and take the steps necessary to ensure the patient's safety. Before opening the tube of catalyst, even it out with your fingers. After opening, eliminate any excess liquid. The catalyst is sensitive to humidity; we recommend you close the tube of catalyst immediately after extruding the material to avoid the nozzle getting clogged. Avoid contact with clothing because the catalyst leaves indelible stains.

200/900 ml/25 kg jars (Protesil Putty)

In order to reduce the risk of cross-contamination, always use new, uncontaminated gloves when handling tubs and accessories. Use with Protesil Catalyst gel only**.** Use the measuring spoon provided by Vannini Dental only.

40/140 ml tubes (Protesil Light)

In order to reduce the risk of cross-contamination, always use new, uncontaminated gloves when handling tubes and accessories. Use with Protesil Catalyst gel only. When using a syringe for use with elastomers, check its compatibility with Condensation Silicones prior to use.

STEP-BY-STEP INSTRUCTIONS:

200/900 ml/25 kg jars (Protesil Putty) – 60 ml tube Protesil Catalyst gel

1. Remove any seals and lids.
2. Use the measuring spoon provided to measure out the base. The measuring spoon should be filled flush with the surface (fig. 1.1).
3. Spread the measured amount on a mixing block or clean surface.
4. Press the edge of the measuring spoon against the material (fig. 1.2). Repeat the procedure for each spoonful measured (fig. 1B). Replace the cap on the tube of base.
5. Open the tube of Protesil Catalyst gel. The catalyst can be supplied separately from the bases of the materials it is combined with for mixing..
6. Spread two parallel strips of Protesil Catalyst gel of the same length as the measuring spoon, taking care to reach the inner edges of the same (equal to 4 cm each) (fig. 1.3). Repeat the procedure for each spoonful measured (fig. 1B).
7. Replace the cap on the tube of Protesil Catalyst gel immediately.
8. Mix the material with the fingertips, by folding it back on itself repeatedly, to achieve an even colour with no streaks (fig. 1.4). Observe the mixing time indicated in the technical data table.
9. Proceed in accordance with the chosen technique.
10. After use, disinfect the impression as described in the disinfection procedure (see paragraphs 9.7 and 9.8) and disinfect the spatula following the instructions provided by the manufacturer.

40/140 ml tubes (Protesil Light) – 60 ml tube Protesil Catalyst gel

1. Remove the base cap. Squeeze a strip of base onto a mixing block or a clean surface. Close the base tube immediately after squeezing out the material.
2. Open the tube of Protesil Catalyst gel. The catalyst can be supplied separately from the bases of the materials it is combined with for mixing.
3. Spread a strip of Protesil Catalyst gel the same length as the strip of base onto the mixing block or clean surface. The length of base to catalyst ratio must be 1:1 (fig. 2.1). Repeat the procedure for each strip of base dispensed (fig. 2B).
4. Replace the cap on the tube of Protesil Catalyst gel immediately.
5. Using a spatula for silicones, mix the base with the catalyst, to obtain an even colour without any streaks (fig. 2.2). Observe the mixing time indicated in the technical data table.

6. Proceed in accordance with the chosen technique.
7. After use, disinfect the impression as described in the disinfection procedure (see paragraphs 9.7 and 9.8) and disinfect the spatula following the instructions provided by the manufacturer.

9.7 DISINFECTING AND CLEANING THE DEVICE: GENERAL PRECAUTIONS/WARNINGS

Use clear, appropriately disinfected/sterilised accessories. The impressions must be disinfected using a disinfectant intended specifically for Condensation Silicones. Use of an unsuitable disinfectant or of the right disinfectant but for too long may compromise the impression.

9.8 DISINFECTING AND CLEANING THE DEVICE: GENERAL STEP-BY-STEP INSTRUCTIONS

1. Rinse the impression thoroughly to remove any residue and traces of saliva (fig. 1C).
2. Remove any excess water.
3. Disinfect the impression using a disinfectant intended specifically for Condensation Silicones (Polysiloxanes), dipping the impression in the solution or spraying it directly if using a spray disinfectant (fig. 2C). Follow the chosen disinfectant manufacturer's instructions for contact time. Quaternary ammonium salt-based disinfectants or mixtures of alcohol and surface tension reducers have been tested. Please refer to the instructions for use for each specific impression disinfectant you wish to use, to check compatibility and effectiveness.

10. TECHNICAL DATA

The times for clinical use and technical data are shown in Table 1.

	Protesil Putty	**Protesil Light**
ISO 4823	Type 0 Putty Consistency	Type 3 Light-bodied Consistency
Mixing time	30"	30"
Minimum processing time* (ISO)	1'	1'
Clinical working time* (including mixing time)	1'15"	1'30"
Time in mouth**	3'30"	3'30"
Setting time	4'45"	5'00"
Elastic recovery	98.5%	98.5%
Shore-A hardness 1 hour	70	30
Mixing ratio	18 g:0.31 g	6.5 g:0.65 g

*****The times are intended from the start of mixing at 23°C/73°F and 50% of relative humidity. Intensive mixing, high temperatures and excessive doses of Protesil Catalyst gel reduce these times. Low temperatures and insufficient doses speed up these times.

****** The time in mouth is intended at 35°C/95°F. Use of larger amounts of Protesil Catalyst gel will shorten this time, use of smaller amounts will extend it.

11. STORAGE AND STABILITY

The devices should be used within a professional dental environment (legally-certified public or private health facilities).

Use the product at an ambient temperature of 23°C/73°F (higher temperatures reduce working time, lower temperatures extend working time). Do not use after the expiry date indicated on the packaging. Store the product at a temperature between 5°C/41°F and 27°C/ 80°F. Do not store the product in direct sunlight. Store the Protesil Catalyst gel in a dry place at a temperature of between 5°C / 41°F and 27°C / 80°F. Do not store the product in the direct sunlight and protect from possible microbial contamination.

12. IMPRESSION CASTING

After completing disinfection, dry the impression before casting the gypsum. It is advisable to cast the impression within 72 hours after the disinfection phase.

It is advisable to cast the impression using gypsum type IV (e.g Elite Rock) or type III (e.g Elite Model) following the manufacturer's instructions.

13. CONSERVATION OF THE IMPRESSION

Store the impressions at ambient temperature, in a dry place away from direct sunlight.

14. IMPORTANT REMARKS

Information provided in any way, even during demonstrations, does not invalidate the instructions for use. Operators are required to check that the product is suitable for the application envisaged. The manufacturer cannot be held responsible for damage, including to third parties, deriving from failure to follow instructions or from unsuitability for an application. The manufacturer's liability is, in any case, limited to the value of the products supplied. Report any serious incident involving the medical device to the manufacturer and to the relevant authorities.



This symbol identifies a medical device as defined by EU Regulation 2017/745.



Three-year shelf-life from the production date.