



VANNINI DENTAL
Industry
Italy

Protesil C-Silicones

c-silicone dental impression material

Protesil Putty

Protesil Light

Protesil Catalyst Gel



VANNINI DENTAL INDUSTRY

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MADE IN ITALY



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IMPRESSION TAKING PROCEDURE

Two-step impression technique (double step impression)



1.1



1.2



1.3



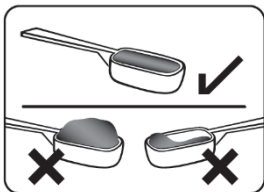
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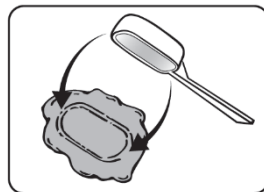
1.5

PREPARING THE DEVICES: STEP-BY-STEP INSTRUCTIONS

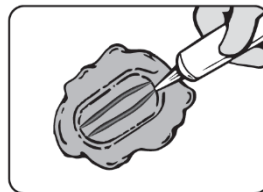
200/900 ml jars (Protesil Putty) – 60 ml tube (Protesil Catalyst Gel)



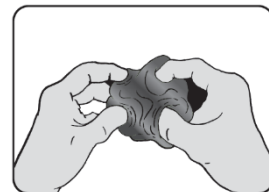
2.1



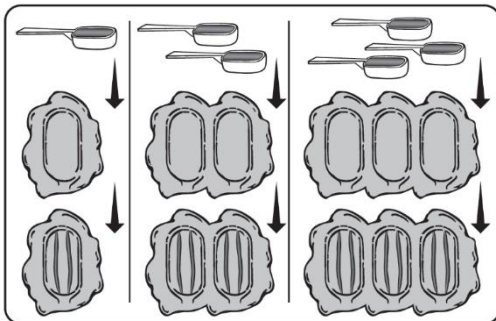
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2.3



2.4

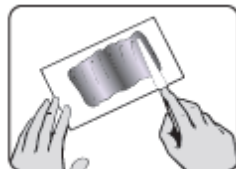


2A

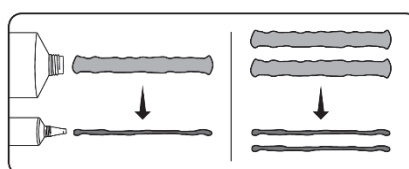
40/140 ml (Protesil Light) – 60 ml (Protesil Catalyst Gel) tubes



3.1



3.2

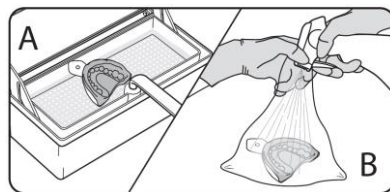


3A

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



4.1



4.2

Protesil C-Silicones

Instructions for use

1. INTENDED USE

Bases: C-silicone dental impression material

Catalyst: Catalyst for C-silicone dental impression material

2. PRODUCT DESCRIPTION

Protesil Putty: A **high viscosity** condensation polysiloxane (base) recommended for taking double step impressions in conjunction with Protesil Light.

Protesil Light: A **low-viscosity** condensation polysiloxane (base) recommended for taking double step impressions in combination with Protesil Putty.

Protesil Catalyst Gel: catalyst for condensation polysiloxanes. Used only for curing the bases: Protesil Putty and Protesil Light. Protesil Catalyst Gel can be supplied separately from the bases with which it is intended for mixing.

3. PACKAGING

200 ml jar of base (Protesil Putty)

900 ml 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, silica fillers, inorganic aluminium fillers, hydrocarbons, additives, pigments, peach flavour.

Protesil Light: polysiloxanes, silica fillers, additives, surfactants, pigments.

Protesil Catalyst Gel: tinorganic compound, alkoxysilanes, hydrocarbons, polysiloxanes, pigments, mint flavour.

5. INDICATIONS FOR USE

The devices are intended to be used in the dental field by professionals working in the dental sector trained and qualified to perform impression taking on dental patients (any age).

6. CONTRAINDICATIONS

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

7. SIDE EFFECTS

Irritation, redness or signs of hypersensitivity may occur in case of allergy to any of the components. Do not swallow. If swallowed, seek medical attention immediately.

8. CLINICAL BENEFITS

Vannini condensation silicones allow accurate recording of the patient's oral tissue and/or prosthetic component dimensions and their spatial relationships.

GENERAL WARNINGS/PRECAUTIONS:

- The instructions for use of the product must be kept for the entire duration of use of the product itself.
- These devices should only be used by professional dental practitioners operating in dental surgeries (public or private health facilities with the necessary legal authorisations).
- In order to reduce the risk of cross-contamination, always use new, uncontaminated gloves when handling the jars, tubes and accessories.
- Do not use the material:
 - if the lot and expiry date on the outer packaging are missing or have been deleted;
 - if the primary packaging (jar, tube) is damaged.
- Safety Data Sheet available on request.

9. STEP-BY-STEP INSTRUCTIONS

9.1 PRELIMINARY OPERATIONS:

1. Read the instructions for use.
2. Disinfect your hands and wear a new pair of disposable gloves. Wear a face mask, protective goggles and work clothes.

9.2 PREPARING THE DEVICE

PRECAUTIONS/WARNINGS ON DEVICE PREPARATION:

- Do not use after the expiry date indicated on the packaging.
- Observe indicated doses. Incorrect doses may influence the material's dimensional stability and polymerisation times.
- As silicones leave indelible marks, avoid contact with clothing.
- Take care to close the tube of the catalyst (Protesil Catalyst Gel) immediately after use to prevent the nozzle from becoming blocked. If, on use, the nozzle appears blocked, do not squeeze the tube hard but dispose of the product as instructed in paragraph 12.
- Avoid direct contact between the catalyst and skin and eyes. In the event of accidental contact with the skin, wash thoroughly with soap and water and seek immediate medical advice. In the event of accidental contact with the skin, wash thoroughly with soap and water.
- Only use Protesil Putty and Protesil Light with Protesil Catalyst Gel.
- Use the measuring spoon provided by Vannini only.
- Check compatibility with accessories not supplied by Vannini (e.g. syringe for elastomer).

Handle and dose outside the operating area and well away from splashes, sprays and aerosols of body fluids:

A. 200/900 ml 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 (Protesil Putty). The measuring spoon should be filled flush with the surface (fig. 2.1).
3. Spread the measured amount on a mixing block or clean surface.
4. Press the edge of the measuring spoon against the material (fig. 2.2). Repeat the procedure for each spoonful measured (fig. 2A). Close the lid of the base.
5. Open the tube of the catalyst (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 catalyst of the same length as the measuring spoon, taking care to reach the inner edges of the same (equal to 4 cm each) (fig. 2.3). Repeat the procedure for each spoonful measured (fig. 2A).
7. Close the cap on the tube of the catalyst immediately.
8. Mix the material with the fingertips, folding it back on itself repeatedly, until an even shade with no streaks is achieved (fig. 2.4). Observe the mixing time indicated in the technical data table.
9. Proceed to use the device on the patient.

B. 40/140 ml TUBES (Protesil Light) - 60 ml TUBE (Protesil Catalyst Gel)

1. Remove the cap of the base (Protesil Light). 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 the catalyst (Protesil Catalyst Gel). The catalyst can be supplied separately from the bases of the materials it is combined with for mixing.
3. Dispense a strip of catalyst of the same length as that of the base on to the mixing block or a clean surface. The ratio between the lengths of base and catalyst must be 1:1 (fig. 3.1). Repeat the procedure for each strip of base dispensed (fig. 3A).
4. Close the cap on the tube of the catalyst immediately.
5. Using a spatula for silicones, mix the base with the catalyst until an even shade with no streaks is achieved (fig. 3.2). Observe the mixing time indicated in the technical data table.
6. Clean, disinfect and, if applicable, sterilize the spatula according to the instructions provided by its manufacturer.
7. Proceed to use the device on the patient

9.3 USING THE DEVICE ON THE PATIENT

PRECAUTIONS/WARNINGS REGARDING USE OF THE DEVICE ON PATIENTS:

- The product is intended for contact with intact mucosa.
- 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.
- In case of use of a resin impression tray, take care, before its use, to remove the first non-polymerized layer with a wipe soaked in ethyl alcohol.
- Do not over-fill the impression tray.
- Do not swallow. If swallowed, seek medical attention immediately.
- Use the product at an ambient temperature of 23°C/73°F (higher temperatures reduce working time, lower temperatures extend working time).

9.4 IMPRESSION TAKING PROCEDURE

Two-phase technique (double step impression):

1. Prepare the **high-viscosity** material to be used for the first impression (see paragraph 9.2 A).
2. Select an impression tray with retention rims.
3. Place a suitable quantity of **high viscosity** material on the impression tray (fig. 1.1).
4. Take the first impression by placing the loaded impression tray inside the patient's mouth within the working time (see paragraph 11, technical data table) (fig. 1.2).
5. Remove the impression from the patient's mouth when the setting time is reached (see paragraph 11, technical data table). Check the integrity of the impression and that no material residues remain in the patient's mouth.
6. Wash the first impression and dry it thoroughly.
7. Process the first impression.
8. Prepare the **low-viscosity** material to be used for the second impression (see paragraph 9.2 B).
9. Apply a suitable quantity of **low-viscosity** material where necessary (preparations, first impression, etc.) (fig. 1.3 and 1.4) and place the reloaded impression tray back inside the patient's mouth to take the second impression within the clinical working time (see paragraph 11, technical data table) (fig. 1.5).
10. Remove the impression from the patient's mouth when the setting time is reached (see paragraph 11, technical data table). Check the integrity of the impression and that no material residues remain in the patient's mouth.
11. Manually clean and disinfect the impression as instructed in paragraph 9.5.

9.5 MANUAL CLEANING AND DISINFECTION OF THE IMPRESSION

PRECAUTIONS/WARNINGS ON MANUAL CLEANING AND DISINFECTION OF THE IMPRESSION:

- Impressions must always be disinfected manually using a specific disinfectant for condensation silicones (polysiloxanes), either in concentrated form based on quaternary ammonium salts and synergic co-formulants (immersion formula) or ready for use, based on alcohol and surface tension reducers (spray formula). Follow the chosen disinfectant manufacturer's instructions for contact time.
- Use of an unsuitable disinfectant or of the right disinfectant for too long may compromise the impression.
- Do not use brushes to remove dirt as this could damage the impression.
- Manual cleaning alone is not sufficient to condition an impression. Cleaning must always be followed by disinfection.
- The impression **MUST NOT BE**:
 - sterilised in an autoclave, with chemical vapour, dry heat and cold chemical immersion sterilizers;
 - cleaned/disinfected in instrument washing machines or thermal disinfection devices;
 - cleaned in ultrasonic baths.
- No automatic methods of cleaning and disinfecting impressions have been validated.
- Impressions must always be cleaned and disinfected before being sent to the laboratory for processing.
- The properly cleaned and disinfected impression must be stored in a closed, dry, clean environment well away from splashes, sprays and aerosols of body fluids and at an ambient temperature of around 23°C / 73°F.

9.5.1 PREPARATION PRIOR TO CLEANING AND DISINFECTION

1. Wear a pair of disposable gloves, a face mask, goggles and work clothes.
2. To disinfect an impression by immersion (**9.5.3 A**), prepare in a basin a specific detergent-disinfectant solution for impressions, approved according to local regulations and based on quaternary ammonium compounds and synergic co-formulants (e.g. Zeta 7 Solution).

9.5.2 MANUAL CLEANING

1. Rinse the impression under running water **for 30 seconds** immediately after removal from the mouth (fig. 4.1). Do not wait more than 5 minutes after removal from the mouth before cleaning the impression.

If necessary, increase rinsing time until no dirt remains visible.

2. Disinfect the impression in the preferred way, either by immersion (see paragraph 9.5.3 A) or spray (see paragraph 9.5.3 B).

9.5.3 MANUAL DISINFECTION OF IMPRESSIONS

A. IMMERSION (fig. 4.2 A)

Always follow the manufacturer's instructions when using immersion type detergents-disinfectants.

1. After cleaning (9.5.2), immerse the impression in the detergent-disinfectant solution (previously prepared as instructed in step 2 of paragraph 9.5.1 PREPARATION PRIOR TO CLEANING AND DISINFECTION).
2. Leave the impression immersed in the prepared solution for the time stated in the instructions for use of the detergent-disinfectant.
3. Rinse and/or dry as instructed.

B. SPRAY (fig. 4.2 B)

Always follow the manufacturer's instructions when using spray type detergents-disinfectants.

1. After cleaning (9.5.2), place the impression in a transparent bag.
2. Insert the nozzle of the spray bottle of detergent-disinfectant for impressions into the transparent bag. Make sure that the spray is approved according to local regulations and based on ethanol, isopropyl alcohol and co-formulants (e.g. Zeta 7 Spray).
3. Hold the bag closed to prevent the aerosol from escaping.
4. Spray in the detergent-disinfectant, taking care to cover the entire surface of the impression and impression tray and respecting the contact times stated in the instructions for use of the detergent-disinfectant.
5. Keep the bag closed and leave the product to act.
6. Remove the impression from the bag and dispose of the bag.
7. Rinse and/or dry as instructed.

10. INFORMATION ON THE CORRECT USE OF PACKAGING AND ACCESSORIES

Product packaging (see paragraph 3) and associated accessories can be re-used safely without special cleaning and disinfection processes provided the following recommendations for preservation, dosing and storage are observed:

- Handle, dose from and store packaging and accessories outside the operating area, in clean facilities and well away from splashes, sprays and aerosols of body fluids;
- Always wear new, uncontaminated gloves when handling packaging and accessories. If gloves become contaminated, change them immediately before handling the product;
- Close packaging immediately after dosing.

Dispose of contaminated products and accessories as instructed in paragraph 12.

11. TECHNICAL DATA

	Protesil Putty	Protesil Light
ISO 4823	Type 0 Putty Consistency	Type 3 Light-bodied Consistency
Mixing time	30"	30"
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	60	30
Mixing ratio	17 g: 0.29 g	6.5 g: 0.65 g

*Times are intended from the start of mixing, at 23°C/73°F and 50% of relative humidity. Intensive mixing, higher temperatures and overdosing of Protesil Catalyst Gel reduce these times. Lower temperatures and underdosing increase these times.

** Time in mouth is intended at 35°C/95°F. Overdosing of Protesil Catalyst Gel shortens this time, underdosing extends it.

12. STORAGE, STABILITY AND DISPOSAL

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 catalyst (Protesil Catalyst Gel) in a dry place at a temperature between 5°C / 41°F and 27°C / 80°F. Do not store the product in direct sunlight. Keep impressions clean and disinfected in a closed, dry place, well away from splashes, sprays and aerosols of body fluid, and at an ambient temperature around 23°C / 73°F. After disinfection, impressions should be used within a maximum of 72 hours.

The following indications for disposal are valid only if the product has been stored and used according to these instructions.

BASE: on the basis of the information provided in the product safety data sheet, the waste generated by disposal of the silicone (base) does not present any physical risks to persons or the environment. The product may therefore be managed as non-hazardous waste, in accordance with the local legislation of reference.

CATALYST: on the basis of the information provided in the product safety data sheet, the waste generated by disposal of the silicone (catalyst) present physical risks to persons or the environment. It must therefore be managed as hazardous waste, in accordance with the local legislation of reference.

Always wear gloves when handling the device.

IMPRESSION: if the impression becomes contaminated, dispose of it as special biological waste.

Uncontaminated impressions may be disposed of in conformity to applicable local regulations.

Refer to paragraph 9.5 of these instructions for information on the management of contaminated components.

13. IMPRESSION CASTING

After completing disinfection, dry the impression before casting the gypsum. Cast the gypsum in an interval between 1 and 72 hours after the impression is removed from the mouth.

Cast the impression with type 3 gypsum (e.g. Elite Model) or type 4 gypsum (e.g. Elite Rock), following the manufacturer's instructions.

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.

	
Wear disposable gloves.	Ukraine Mark of Conformity