VANNINI DENTAL
Industry
Italy

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ADDITION SILICONES FOR DENTAL IMPRESSIONS

PRESTIGE

PRESTIGE PUTTY

PRESTIGE PUTTY SOFT

PRESTIGE A PLUS PUTTY

PRESTIGE REGULAR

PRESTIGE REGULAR FAST

PRESTIGE LIGHT

PRESTIGE A PLUS LIGHT

PRESTIGE HYDROLIGHT

PRESTIGE MINI KIT

PRESTIGE MINI KIT SOFT

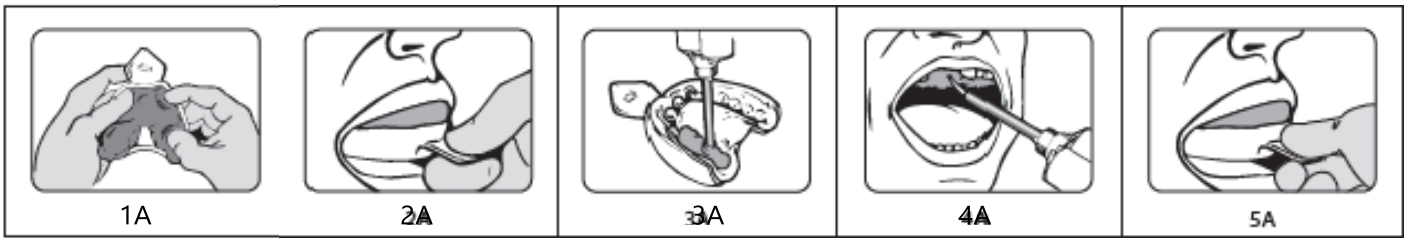
PRESTIGE A PLUS MINI KIT

PRESTIGE MONOPHASE

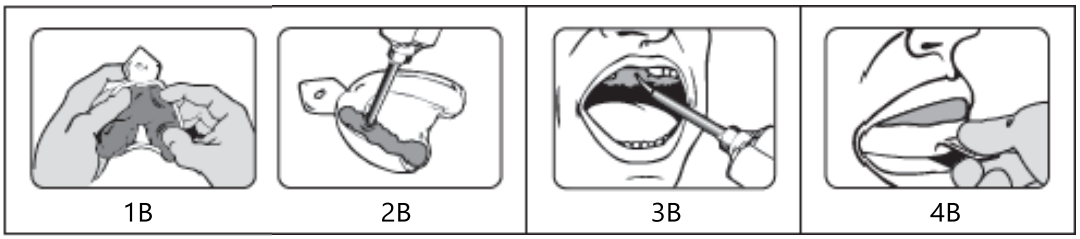
Rev. 07/2022

IMPRESSION TAKING PROCEDURE

Two-phase technique (double impression):

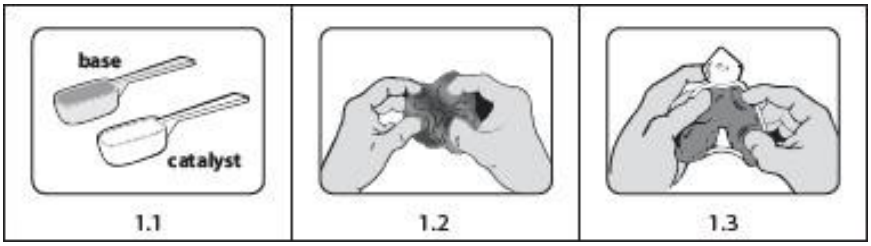


Monophase technique (simultaneous):

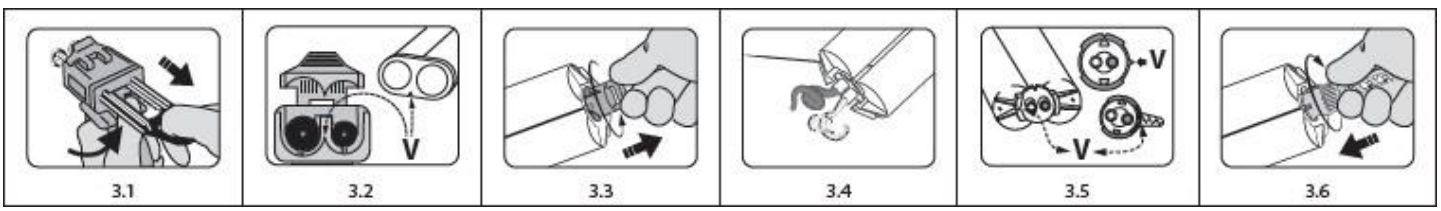


Preparation:

300 ml + 300 ml jars (Prestige Putty / Prestige Putty Soft); 200 ml + 200 ml jars (Prestige A Plus Putty)

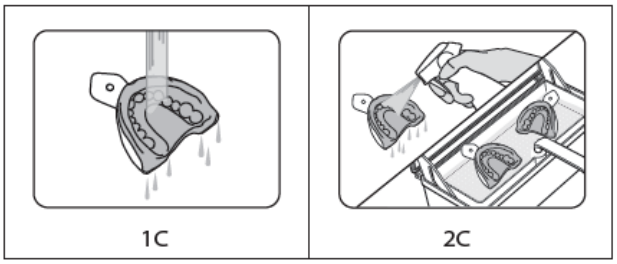


1:1 50 ml cartridges (Prestige Light Body/Prestige A Plus Light / Prestige Monophase/ Prestige Regular Body/ Prestige Light Body/ Prestige Hydrolight)



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DISINFECTING AND CLEANING THE DEVICE:



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Instructions for use

1. **INTENDED USE**

Addition silicones for dental impressions.

2. **PRODUCT DESCRIPTION**

Putty / Putty Soft (mixing ratio 1:1): **high viscosity** vinyl polysiloxane, recommended for the two-phase (double impression) technique in combination with Prestige Light o Prestige Hydrolight Body fluids, or Prestige Monophase (simultaneous) technique in combination with Prestige Regular o Prestige A Plus Light.

Monophase (mixing ratio 1:1): **medium viscosity** vinyl polysiloxane, recommended for the monophase technique as a single viscosity material.

Regular Body (mixing ratio 1:1): medium viscosity vinyl polysiloxane, recommended for the monophase (simultaneous) technique, in combination with Prestige Putty /Prestige Putty Soft.

Light Body (mixing ratio 1:1): **low viscosity** vinyl polysiloxane, recommended for the two-phase (double impression) technique or the monophase (simultaneous) technique in combination with Prestige Putty /Prestige Putty Soft.

3. **PACKING**

Product name	**Cod.**	**Packaging**
Prestige Putty	055001	2 jars x 300 ml / 450g (Base + catalyst)
Prestige Putty Soft	055002	2 jars x 300 ml / 450g (Base + catalyst)
Prestige Light	055106 055206	2 cartridges x 50 ml + 12 mixing tips 2 cartridges x 50 ml
Prestige Regular	0055105 055205	2 cartridges x 50 ml + 12 mixing tips 2 cartridges x 50 ml
Prestige Monophase	055010	2 cartridges x 50 ml + 12 mixing tips

	055210	2 cartridges x 50 ml
Prestige Hydrolight	055107 055250	2 cartridges x 50 ml + 12 mixing tips 2 cartridges x 50 ml
Prestige Regular Fast	055505	2 cartridges x 50 ml + 12 mixing tips
Prestige A Plus Putty	055101	2 jars x 200 ml / 335g (Base + catalyst)
Prestige A Plus Light	055108	2 cartridges x 50 ml + 6 mixing tips

4. COMPOSITION

PRESTIGE A PLUS LIGHT:
Vinylpolysiloxane, Silica Fillers, Inorganic Aluminium Fillers, Methylhydrogensiloxane, Surfactant, Organoplatinic complex, Pigments, Flavours (Vanilla and wild strawberry)

PRESTIGE LIGHT FAST / PRESTIGE HYDROLIGHT FAST/ PRESTIGE REGULAR FAST AND REGULAR / PRESTIGE MONOPHASE:
Vinylpolysiloxane, Silica Fillers, Inorganic Aluminium Fillers, Methylhydrogensiloxane, Surfactant, Organoplatinic complex, Pigments

PRESTIGE PUTTY SOFT / PRESTIGE PUTTY
Vinylpolysiloxane, Silica Fillers, Inorganic Aluminium Fillers, Methylhydrogensiloxane, Hydrocarbons, Organoplatinic complex, Pigments

PRESTIGE A PLUS PUTTY
Vinylpolysiloxane, Silica Fillers, Inorganic Aluminium Fillers, Methylhydrogensiloxane, Hydrocarbons, Organoplatinic complex, Pigments, Flavours (Vanilla and wild strawberry)

5. INSTRUCTIONS FOR USE

The devices are intended for use in dentistry by trained and qualified professionals for the purpose of impression taking on dental patients.

6. CONTRAINDICATIONS

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

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 hardening of Addition Silicones (Vinyl polysiloxanes) is inhibited by contact with gloves or other items made of latex. Avoid direct or indirect contact with items made of latex. Wash your hands thoroughly to eliminate all traces of contaminants and wear vinyl or nitrile gloves. Use an adhesive specifically for use with

Addition Silicones (Vinyl polysiloxanes). Check compatibility prior to use. The product is safe for use on intact mucous membranes.

9.2 GENERAL PRECAUTIONS/WARNINGS ON THE PREPARATION OF THE DEVICE:

Store the product at a temperature between 5°C and 27°C. Do not store the product in direct sunlight. Do not use after the expiry date specified 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 material if it is visibly inconsistent. The product has not been tested for compatibility with accessories other than those with which it is supplied. Use of non-original accessories may cause events that lead to a reduction in the precision of the impression. The use of non-original accessories is therefore not recommended. 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 overfill the impression tray, as this could cause ingestion and trigger the patient's emetic reflex.

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

Use on patients sensitive to Addition Silicones (Vinyl polysiloxanes) is not recommended. If irritation, redness or other signs of hypersensitivity occur, stop using the product and take the steps necessary to ensure the patient’s safety. Avoid taking multiple impressions in a single session to help prevent irritation of the oral mucous membranes. Avoid taking more than three impressions in the same arch/area in a single session. In the presence of symptoms, discontinue use immediately. In order to avoid complications, it is advisable to block excessive undercuts before taking the impression. The hardening of Addition Silicones (Vinyl polysiloxanes) is inhibited by contact with latex, sulphur-based gingival retraction solutions, polyethers and the unpolymerized surface of acrylic or bis-acryl resins. Avoid direct or indirect contact of the material with these substances. Should the patient's hard and soft oral tissues or accessory surfaces with which the material comes into contact be contaminated with these substances, clean them thoroughly with water, or with ethyl alcohol/other solvents in the case of acrylic or bis-acryl resins. When using haemostatic and astringent substances, check their compatibility with Addition Silicones (Vinyl polysiloxanes) prior to use.

9.4 PRELIMINARY OPERATIONS:

1. Read the instructions for use.
2. Use compatible protective gloves, face mask, eyewear and work clothes.
3. Select the impression tray you wish to use.
4. Apply an adhesive specifically for use with addition silicones to the impression tray and leave to dry according to the adhesive manufacturer's instructions.
5. Then choose the impression technique to be used.

9.5 IMPRESSION TAKING PROCEDURE

Two-phase technique (double impression):

1. Prepare the device of the high viscosity material 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 high viscosity material on the impression tray.
4. Take the first impression by inserting the impression tray into the patient's mouth.
5. Remove the impression from the patient's mouth when the setting time has been reached (see paragraph 10, technical data table).
6. Process the first impression.
7. Wash the first impression and dry it thoroughly.
8. Prepare the device of the **low viscosity** material 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 inside the patient's mouth to take the second impression within the clinical processing 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.

Monophase technique (simultaneous):

13. Prepare the high and low viscosity material devices to be used for the impression. See paragraph 9.6 for details on how to prepare the device. For the monophase technique, prepare the monophase viscosity material.
14. Mix the impression materials, observing the mixing times (see paragraph 10, technical data table).
15. Place a suitable amount of the higher viscosity material on the impression tray (fig. 1B) and apply the lower viscosity material where necessary in the patient's mouth (preparations, transfer, etc.) (fig. 2B). Place the impression tray inside the patient's mouth within the clinical processing time (see paragraph 10, technical data table) (fig. 3B).
16. Remove the impression from the patient's mouth when the setting time has been reached (see paragraph 10, technical data table).
17. 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 in paragraph 10 for each phase.

9.6 PREPARING THE DEVICES

300 ml + 300 ml jars (Prestige Putty / Prestige Putty Soft); 200 ml + 200 ml jars (Prestige A Plus Putty)

SPECIFIC WARNINGS:

The two components of the device (base and catalyst) must be used in equal parts to obtain the right setting times and not alter the performance of the product; a higher dose of catalyst does not accelerate the hardening time. **DO NOT SWAP OVER THE LIDS AND COVER DISCS** (where present) as this could lead to the unintentional polymerization of the product inside the jar.

STEP-BY-STEP INSTRUCTIONS:

1. Remove seals and lids (including cover discs and films where present).
2. Take the two components (base and catalyst) in equal parts **USING THE CORRESPONDING COLOUR SPOON** (fig. 1.1).
3. Close the jars. **DO NOT SWAP OVER THE LIDS AND COVER DISCS** (where present).
4. Mix together equal amounts of Base and Catalyst, until you obtain an evenly coloured mass without streaks (fig. 1.2). Observe the mixing time indicated in the technical data table. Proceed in accordance with the chosen technique (fig. 1.3).
5. After use, disinfect the impression as described in the disinfection procedure. (see paragraphs 9.7 and 9.8).

1:1 50 ml CARTRIDGES (Prestige Light Body/Prestige A Plus Light / Prestige Monophase/ Prestige Regular Body/ Prestige Hydrolight).

SPECIFIC WARNINGS:

Always (before each use) balance the material (fig. 3.4) before inserting the mixing tip. When applying the material, take care to keep the mixing tip immersed inside it.

STEP-BY-STEP INSTRUCTIONS:

1. Pull the elastomer dispenser rack as far back as it will go by raising the black lever below it. Lift the cartridge lock (fig. 3.1).
2. Insert the cartridge making sure that it fits the right direction. The cartridge must be inserted with the "V" on its base facing downwards. The cartridge lock can now be lowered easily (fig. 3.2).
3. After placing the cartridge on the dispenser, turn the cap by a 1/4 turn, pull it out with a firm movement and throw it away (fig. 3.3).
4. Press the dispenser lever gently to squeeze out a small amount of the two components until they both emerge at the same time. Remove any excess, taking care not to contaminate the two holes (fig. 3.4).
5. Select the appropriate mixing tip; the colour of the tip must be the same as the colour of the cartridge cap.
6. Insert the mixing tip in a clean motion so that the V-shaped notch on the coloured ring aligns with its housing on the cartridge (fig. 3.5). Turn the tip clockwise by a 1/4 turn, exerting pressure only on the coloured ring and not on the mixing tip itself (fig. 3.6). Use the intraoral tip with the yellow tip for more accurate application.
7. It is advisable to protect the dispenser, cartridge and tip with disposable cellophane, removing it after each use.
8. Press the dispenser lever gently to squeeze out an appropriate amount of material. Proceed in accordance with the chosen technique.
9. Wait for the material to polymerize, observing the time indicated in the table.
10. Remove the impression from the patient's mouth.
11. After use, keep the tip on the cartridge until the next use and thoroughly disinfect the tip, impression and dispenser as described in the disinfection procedure (see paragraphs 9.7 and 9.8).

9.7 DISINFECTING AND CLEANING THE DEVICE: GENERAL PRECAUTIONS/WARNINGS

The impressions must be disinfected using a disinfectant specifically for Addition Silicones (Vinyl polysiloxanes). 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

Rinse the impression thoroughly to remove any residue and traces of saliva (fig. 1C). Remove any excess water. Disinfect the impression using a disinfectant specifically for Addition Silicones (Vinyl 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.

For **1:1 50 ml cartridges**: disinfect the tip without removing it from the cartridge, leaving it in place after disinfecting it. Before the next use of the cartridge, remove the old mixing tip and fit a new one.

Disinfect the dispenser according to the manufacturer's instructions. Do not disinfect the cartridge directly to avoid erasing important information (lot and expiry date).

10. TECHNICAL SPECIFICATIONS

11. DATI TECNICI

	Prestige Putty	Prestige A Plus Putty	Prestige Putty Soft	Prestige Monophase	Prestige Regular Fast	Prestige Regular	Prestige Light	Prestige A Plus Light	Prestige Hydrolight
	Regular Set	Regular Set	Fast Set	Fast Set	Fast Set	Regular Set	Fast Set	Regular Set	Fast Set
ISO 4823	Type 0	Type 0	Type 0	N/A	Type 2	Type 2	Type 3	Type 3	Type 3
	Putty Consistency	Putty Consistency	Putty Consistency		Medium-Bodied Consistency	Medium-Bodied Consistency	Light-Bodied Consistency	Light-Bodied Consistency	Light-Bodied Consistency
Mixing ratio Base : Catalyst	01:01	01:01	01:01	01:01	01:01	01:01	01:01	01:01	01:01
Mixing time	30"	30"	30"	0"	0"	0"	0"	0"	0"
Minimum processing time (ISO)	1'	1'	1'	1'	1'	1'	1'	1'	1'
Clinical processing Time (including mixing time)	2'	2'	1'30"	1'30"	1'30"	2'	1'30"	2'	1'30"
Time in the oral cavity (min.)	3'30"	3'30"	2'30"	2'30"	2'30"	3'30"	2'30"	3'30"	2'30"
Setting time*	5'30"	5'30"	4'	4'	4'	5'30"	4'	5'30"	4'
Elastic recovery	99%	99%	99%	99%	99%	99%	99%	99%	99,50%
Linear dimensional change 24 h	0,25%	0,25%	0,25%	0,25%	0,25%	0,25%	0,25%	0,25%	0,25%
Shore-A hardness 1 hour	75	65	60	70	55	55	50	50	45

*The times mentioned above are intended from the start of mixing at 23°C/73°F. Higher temperatures reduce these times, lower temperatures extend them.

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 specified on the packaging. Store the product at a temperature between 5°C and 27°C, away from direct sunlight.

12. IMPRESSION CASTING

After completing disinfection, dry the impression before casting the gypsum. It is advisable to cast the impression, waiting for at least 20 minutes using type III gypsum (e.g. Elite Model) or type IV gypsum (e.g.Elite Rock), 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. Users are required to check that the product is suitable for the foreseen application. 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.

