

# Reprosil® Putty

## Vinyl Polysiloxane Impression Material

DENTSPLY  
CAULK

### DIRECTIONS FOR USE – ENGLISH

**Caution:** U.S. federal law restricts this device to sale by or on the order of a dentist.

### DESCRIPTION

Reprosil® Putty is a Vinyl Polysiloxane Impression Material that has a very high viscosity, which provides excellent dimensional accuracy and stability. It consists of two pastes, which when hand-mixed will harden to form a base for final impressions. It is suitable for use as the tray material in the putty/wash impression techniques for reproduction of teeth prepared for crowns, fixed bridges as well as both partial and complete removable prosthodontics. Reprosil® Putty is compatible with other viscosities of Reprosil®, and Aquasil Ultra Smart Wetting® Impression Materials.

Reprosil® Impression Material is to be used following the application of a suitable tray adhesive such as Caulk® Tray Adhesive or Silfix Tray Adhesive. Use of other tray adhesives with Reprosil® Impression Material is at the discretion and sole responsibility of the dental practitioner.

### COMPOSITION

Polydimethylsiloxane polymer; Silicon Dioxide; Polymethylhydrogen Siloxane; Plasticizer; Pigments

### INDICATIONS FOR USE

Reprosil® Putty Material is designed as a tray material for use in conjunction with a compatible lower viscosity wash material for the fabrication of all tooth, implant (closed flap) or tissue crown and bridge impressions, edentulous impressions and the precise duplication of models.

1. Dual phase (Putty/Wash), two-step full arch or quadrant arch impression technique with Light or Medium Body Reprosil® or Aquasil Ultra syringe (wash) impression material.
2. Dual phase (Putty/Wash), one-step full arch or quadrant arch impression technique with Light or Medium Body Reprosil® or Aquasil Ultra syringe (wash) impression material.
3. Border molding/edentulous and abutment/tissue overdenture impression technique with Light or Medium Body Reprosil® or Aquasil Ultra syringe (wash) impression material.
4. Dual phase (Putty/Wash) two-step technique with Light or Medium Body Reprosil® or Aquasil Ultra syringe (wash) impression material for precise duplication of models.

### CONTRAINDICATIONS

None known.

### TECHNICAL DATA

ISO 4823:1992.....	Type 0: Putty
Working Time* (22°C/72°F).....	1 minute 30 seconds from start of mix (room temperature mixing and preparation)
Setting Time (Mouth Removal Time).....	6 Minutes from start of mix
% Recovery from deformation.....	>96.5%
% Strain in compression.....	1.6 –2.2 maximum
Detail Reproduction.....	< 20 microns
% Linear dimensional change.....	<0.5% maximum
Mixing ratio by volume.....	1 part base to 1 part catalyst

### WARNINGS

1. Avoid prolonged or repeated exposure of the Reprosil® impression material with skin and eyes. Irritation and possible corneal damage may result. Skin rash, oral mucosa irritation or other allergic reactions may result in susceptible individuals.  
**Eye and Skin contact:** Flush eyes with flowing water for 15 minutes and consult a physician. Flush skin with flowing water for 15 minutes, then wash area with soap and water after contact. Flush oral tissues with copious amounts of water. Consult a physician if rash persists.  
**Ingestion:** Do not swallow or take internally. If accidental swallowing occurs, drink lots of water. This material is not hazardous when small quantities are ingested. Larger quantities may cause bowel obstruction. Seek medical attention in the event of digestive irregularities.
2. Do not use Reprosil® Impression Material as a temporary reliner. Use of the material in this manner may cause irritation to the oral mucosa. If symptoms occur discontinue use immediately. If irritation does not subside consult a physician.

### PRECAUTIONS

1. This product is intended to be used only as specifically outlined in the *Directions for Use*. Any use of this product inconsistent with the *Directions For Use* is at the discretion and sole responsibility of the practitioner.
2. Reprosil® Material should not be intermixed with, or used in conjunction with other manufacturer's vinyl polysiloxanes. Reprosil® Material should not be intermixed with, or used in conjunction with conventional polyether, polysulfide, or (condensation-cured) silicones.
3. Insufficient data exist to support the use of Reprosil® Impression Materials for impressions on exposed bone. Reprosil® Material should only be used on or around intact mucosa.
4. Never interchange different lots of Reprosil® Material base and catalyst. Unpredictable work and/or set times may result.

5. Allow Reprosil® Material to reach room temperature prior to use. Variations in temperature and mixing speed will affect work time and set time. Higher temperatures and rapid, vigorous mixing reduce available time (accelerate set). Lower temperatures increase them (slower). Clinically, intraoral set time (Mouth Removal Time) is unaffected within the range of allowable storage and initial mixing temperatures.
6. To obtain optimum physical properties, material should be mixed in equal volumes (1:1). Minor variations will not affect work time or set time. The mix should be completely homogenous (streak free).
7. Do not wear latex or "sulfur-containing" polymeric gloves while mixing or handling putty. These may chemically interfere with the setting reaction. Vinyl or other non-latex gloves worn during mixing will avoid this possibility.
8. Use of some hand soaps and lotions can lead to interference with setting reaction. Contamination may accumulate on the surface of the skin and may not easily wash off. Non-latex gloves worn during mixing will avoid this possibility.
9. Do not contaminate retraction cords with latex or "sulfur-containing" polymeric gloves. Handle cords with college pliers. Do not touch prepared tooth with gloves.
10. If the preparation is treated with hydrogen peroxide, rinse with copious amounts of water before making the impression.
11. Reprosil® Material should be used with suitable impression trays pre-treated with Tray Adhesive (see step-by-step instructions). Refer to tray adhesive manufacturer's *Direction for Use* for compatibility.
12. Two-step technique is NOT recommended for double arch trays. When used as a primary impression, material should be covered with a polyethylene spacer sheet, and protected from direct contact with oral tissue. (See *complete Directions For Use*)
13. **Storage:** Store Reprosil® Impression Material at or below room temperature (25°C/77°F). Refrigerated storage is acceptable when not in use. Allow material to reach room temperature prior to use. Keep out of sunlight. Work time is affected by temperature. (See *Precautions, Step-by-Step Instructions*). Protect from moisture. Do not freeze. Do not use after expiration date.

### ADVERSE REACTIONS

1. Corneal damage may result with prolonged eye exposure to the impression material. (See *Warnings*)
2. Allergic contact dermatitis and other allergic reactions may occur in susceptible individuals. (See *Warnings*)
3. Skin irritation may result from direct exposure and skin defatting from prolonged exposure. (See *Warnings*)
4. Bowel obstruction or other digestive distress may result from ingestion of mixed impression material. (See *Warnings*)

### STEP-BY-STEP INSTRUCTIONS

#### Impression Techniques

#### 1. Putty/Wash Dual Phase Two Step Technique

Overview: The two step putty wash technique separates the impression technique into two steps:

- Formation of the custom putty tray impression with relief and;
- The injection of wash material around the prepared teeth and placement of wash material into the custom putty tray impression for seating into the mouth.

**Technique Tip:** It is highly recommended to utilize an assistant with a second dispensing gun to ensure simultaneous syringing and tray loading.

- 1.1 Select and/or prepare a suitable metal tray, a firm disposable tray or a custom tray. Use rigid trays of sufficient size to provide at least 2-3mm thickness of impression material.  
**NOTE:** Two-step procedure is NOT recommended for double-arch trays.
- 1.2 Brush a thin layer of Tray Adhesive (available separately) onto tray following manufacturer's *Directions for Use*. Adhesive should be used even with perforated trays.
- 1.3 If there is any debris or blood clean the field with air water spray.
- 1.4 Remove excess water with suction. **Do not desiccate the tooth.** Dry the field and place cotton rolls.
- 1.5 Using supplied scoops, dispense equal amounts of Reprosil® Putty base and catalyst onto a mixing pad. Close tubs immediately. Do not interchange base and catalyst screw caps or scoops. With clean hands, or wearing non-latex gloves, knead material together approximately 45 seconds until a uniform, streak-free color is achieved. Alternatively, material may be mixed on the pad with a stiff spatula. Apply an even layer into tray. Avoid incorporating air. Place one or more polyethylene plastic sheets over the putty surface. This sheet will create the uniform spacing required for this technique and eliminate the need for trimming the material after the set. It also protects the surface from contamination with saliva and thus ensures a good adherence of the wash material to the putty tray.
- 1.6 Remove cotton rolls. Place the covered tray into the mouth and press over the arch of teeth. After vertical seating, move the tray slightly from side to side and forward and back. This movement will insure the spacing needed for the wash material. Remove from the mouth when material has reached rubbery consistency, and set aside. Do not disturb impression until material has completely set (6 minutes from start of mix).

Variations in temperature will affect work and set times. **Higher temperatures reduce work times and lower temperatures increase them.** Rapid kneading/spatulation and/or smaller amounts mixed e.g. quadrant vs. full arch may also reduce work time.

- 1.7 Remove the polyethylene sheet after the putty material has set. Rinse primary impression with water and air dry.
- 1.8 Dispense Reprosil® Light Body, Aquasil Ultra XLV or Aquasil Ultra LV Regular Set (see complete *Directions for Use*) material directly into the syringe by backfilling the impression syringe or attach an intraoral tip to the end of the mix tip for direct intraoral syringing from a cartridge or prepare digit™ Targeted Delivery System Unit Dose Dispensed syringe (available separately).
- 1.9a Dispense Reprosil®, or Aquasil Ultra Light Body Material (assistant) directly into putty impression.
- 1.9b It is suggested to simultaneously syringe (dentist) completely around the margins of the preparation/abutment, making sure to keep intraoral tip within impression material. Inject syringe material into any existing anatomy and continue syringing around the preparation(s)/abutment(s) until the preparation(s)/abutment(s) is completely covered with syringe material.
- 1.10 Seat loaded tray. Tray must be seated within the intraoral work time of the selected wash material (see complete *Directions for Use* of selected wash material). Retain impression in position without excessive pressure until firmly set. (**NOTE:** The material sets faster in the mouth than on the bench.) Check impression in the mouth (not on the bench) to be sure it is firm, resilient, and non-tacky before removal. See complete *Directions for Use* for the wash material chosen to determine minimum removal time. Variations in temperature will affect work and set times. **Higher temperatures reduce work times and lower temperatures increase them.**
- 1.11 Remove impression by pulling slowly to break seal, then snap out along the long axis of the tooth. Rinse impression under cold water and air dry.

## 2. Putty/Wash Dual Phase One Step Technique

Overview: In this technique both the putty and wash material are simultaneously placed into the mouth. It is recommended that two operators be used for this technique. The timing of events in this technique is critical. A delay inserting the tray loaded with putty material beyond 1 minute 30 seconds **OR** injected wash work time will lead to distortion and ill fitting crowns and bridges.

**Technique Tip:** It is highly recommended to utilize an assistant to ensure simultaneous syringing and tray loading.

- 2.1 Select and/or prepare a suitable tray. Use rigid trays of sufficient size to provide at least 2-3 mm thickness of impression material.
- 2.2 Brush a thin layer of Tray Adhesive (available separately) onto tray following manufacturer's *Directions for Use*. Adhesive should be used even with perforated trays.
- 2.3 If there is any debris or blood clean the field with air water spray.
- 2.4 Remove excess water with suction. **Do not desiccate the tooth.** Dry the field and place cotton rolls.
- 2.5 Using supplied scoops, dispense equal amounts of Reprosil® Putty base and catalyst onto a mixing pad. Close tubs immediately. Do not interchange base and catalyst screw caps or scoops.
- 2.6 Dispense Reprosil® Light Body, Aquasil Ultra XLV or Aquasil Ultra LV Regular Set (see complete *Directions for Use*) directly into the syringe by backfilling the impression syringe or attach an intraoral tip to the end of the mix tip for direct intraoral syringing from a cartridge or prepare digit™ Targeted Delivery System Unit Dose Dispensed syringe.
- 2.7 With clean hands, or wearing non-latex gloves, knead material together approximately 45 seconds until a uniform, streak-free color is achieved. Alternatively, material may be mixed on the pad with a stiff spatula. Apply an even layer into tray. Avoid incorporating air. Create a smooth dimple in the material in the area if the preparation(s)/abutment(s). **NOTE:** Do NOT apply polyethylene spacer.
- 2.8a Remove cotton rolls. It is suggested to simultaneously syringe (dentist) completely around the margins of the preparation/abutment, making sure to keep intraoral tip within impression material. Inject syringe material into any existing anatomy and continue syringing around the preparation(s)/abutment(s) until the preparation(s)/abutment(s) is completely covered with syringe material.
- 2.8b Meanwhile, the assistant should place more of the wash material into the depression in the putty. **THE PUTTY TRAY SHOULD BE INSERTED INTO THE MOUTH IMMEDIATELY AT THE COMPLETION OF SYRINGING, ALWAYS WITHIN INTRAORAL WORK TIME OF WASH MATERIAL, NO LATER THAN 1 MINUTE 30 SECONDS FROM START OF THE PUTTY MIXING.** If placed earlier, the putty will have less viscosity and more flow; if placed later than 1'30" significant distortion may occur and lead to inaccurate impressions. **NOTE:** This timing may require a slight delay in intraoral syringing, so that 1'15"-1'30" from start of putty tray material mixing occurs within the intraoral work time of the selected wash (syringe) material. See complete *Directions for Use* of selected wash/syringe material
- 2.9 Seat loaded tray. Retain impression in position until firmly set. (**NOTE:** The material sets faster in the mouth than on the bench.) Check impression in the mouth (not on the bench) to be sure it is firm, resilient, and non-tacky before removal. The minimum removal time of Reprosil® Putty Impression Material is 6 minutes from the start of mix. Observe the Minimum Removal Time of the light body material selected (if greater than 6 minutes). Variations in temperature will affect work and set times. **Higher temperatures reduce work times and lower temperatures increase them.**
- 2.10 Remove impression by pulling slowly to break seal, then snap out along the long axis of the tooth. Rinse impression under cold water and air dry.

## 3. Border Molding Technique

- 3.1 Brush a thin layer of Tray Adhesive (available separately) onto the borders of the selected (custom or well-adapted stock) tray.
- 3.2 Dispense equal amounts of base and catalyst onto a mixing pad and mix with a stiff spatula or, with clean hands or wearing non-latex gloves, knead by hand until a uniform color is obtained. **NOTE:** Due to smaller volumes used and rapid mixing and manipulating, work time may be less than 3 minutes.

- 3.3 Roll the mix into a thin rope and apply uniformly to the tray borders.
- 3.4 Border molding the entire periphery of the tray is recommended. **Technique Tip:** It is recommended that border molding be accomplished on 1/3 of the tray border per mix.
- 3.5 Instruct patient to perform the various functional movements necessary for conventional border molding techniques.
- 3.6 Once material has reached a rubbery consistency, remove tray and examine borders. The addition of a small mix can be used if voids or deficient areas are present. Over-extensions can be easily removed with a scalpel blade. Repeat until entire tray borders are properly extended.
- 3.7 Once border material has fully set (at least 6 minutes from the start of the last mix) the final impression can be made with Light Body or Medium (Regular) Body Reprosil®, Aquasil Ultra XLV, LV or Monophase material (see complete *Directions for Use* for selected wash material). Apply Tray Adhesive to tray, following manufacturer's *Directions for Use*. Avoid placement on material forming borders. Dispense wash material onto the impression tray. Do not layer the material or place it into rows. This technique ensures the least amount of air incorporation.
- 3.8 Seat loaded tray. Retain impression in position until firmly set. (**NOTE:** The material sets faster in the mouth than on the bench.) Check impression in the mouth (not on the bench) to be sure it is firm, resilient, and non-tacky before removal. See complete *Directions for Use* for the wash material chosen to determine minimum removal time. Variations in temperature will affect work and set times. **Higher temperatures reduce work times and lower temperatures increase them.**
- 3.9 Remove impression by pulling slowly to break seal, then snap out of the mouth. Rinse impression under cold water and air dry.

## 4. Duplication of Models

- 4.1 Select and/or prepare a suitable tray. Use rigid trays of sufficient size to provide at least 2-3mm thickness of impression material.
- 4.2 Brush a thin layer of Tray Adhesive (available separately) onto tray following manufacturer's *Directions for Use*. Adhesive should be used even with perforated trays.
- 4.3 Load the impression tray with mixed Reprosil® Putty Material. Do not layer the material or place it into rows. This technique ensures the least amount of air incorporation.
- 4.4 Place one or more polyethylene plastic sheets over the putty surface. This sheet will create the uniform spacing required for this technique and eliminate the need for trimming the material after the set.
- 4.5 Place the covered tray onto the model. After vertical seating, move the tray slightly from side to side and forward and back. This movement will insure the spacing needed for the wash material. Remove from the model at the end of 6 minutes from the start of mix and set aside. Remove the polyethylene sheet after the putty material has set.
- 4.6a Dispense Reprosil® Regular, Light Body, Aquasil Ultra XLV, or LV Material directly into putty impression. Do not layer the material or place it into rows. This technique ensures the least amount of air incorporation.
- 4.6b It is suggested to simultaneously syringe wash material completely around the model teeth, making sure to keep the tip within the impression material. Inject syringe material into any existing anatomy and continue syringing around the teeth until they are completely covered with syringe material.
- 4.7 Seat model into loaded tray. Retain impression in position until firmly set. (**NOTE:** The material sets slower on the bench than in the mouth.) Check impression to be sure it is firm, resilient, and non-tacky before removal. See complete *Directions for Use* for the wash material chosen to determine minimum removal time. Variations in temperature will affect work and set times. **Higher temperatures reduce work times and lower temperatures increase them.**
- 4.8 Remove model from impression by pulling slowly to break seal.

## CLEANING AND DISINFECTION

### Cleaning Instructions

The tightly closed tubs may be cleaned by wiping with a towel soaked with hot water and soap or detergent. Tubs should be wiped, not immersed. Tubs exposed to splatter or spray of body fluids or if touched by contaminated hands, or oral tissues, should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are those that are EPA-registered as tuberculocidal. Iodophors, sodium hypochlorite (5.25%), chlorine dioxide and dual or synergized quaternary ammoniums are approved disinfectants. Water-based disinfectant solutions are preferred. Use impregnated wipes, not sprays.

**NOTE:** Wipe tubs GENTLY, vigorous wiping may destroy the label.

Some phenolic-based agents and iodophor-based products may cause surface staining. Agents containing organic solvents, such as alcohol may tend to dissolve the plastic. The disinfectant manufacturer's directions should be followed properly for optimum results.

**Technique Tip:** Unset Reprosil® Impression Material can be removed from clothing with dry cleaning solvent.

### Disinfection of the Impression Material

The impression should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are those that are EPA-registered as tuberculocidal. Iodophors, sodium hypochlorite (5.25%), chlorine dioxide, and dual or synergized quaternary ammoniums are approved disinfectants. To disinfect polyvinyl siloxane material, thoroughly soak by spraying or immerse the impression in any recommended hospital level disinfectant except neutral glutaraldehyde for the contact time recommended by the disinfectant manufacturer for optimum results. Water-based disinfectant solutions are preferred.

### **CASTING AND ELECTROPLATING**

The impression should be removed from the disinfectant, rinsed with water and exposed to air to dry for at least the same amount of time it was exposed to the disinfectant solution before it is poured. To avoid surface porosity in stone, delay pour 15 minutes; for epoxy dies, delay pour 60 minutes. The impression may be poured up to 14 days. Do not store impression in direct sunlight. If the impression is to be shipped, use suitable packaging to preclude distortion. The material is compatible with a range of die stones. Impressions may be silver or copper-plated.

### **LOT NUMBER AND EXPIRATION DATE**

1. Do not use after expiration date. ISO standard uses: "YYYY/MM."
2. The following numbers should be quoted in all correspondences:
  - Reorder number
  - Lot number on the container
  - Expiration date

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