Hydrosil®

DENTSPLY CAULK

Hydromonophase Vinyl Polysiloxane Impression Material

DIRECTIONS FOR USE – ENGLISH

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

DESCRIPTION

Hydrosil® Hydromonophase Vinyl Polysiloxane Impression Material is a hybrid elastomeric-type impression material. It is chemically a vinyl polysiloxane like Reprosil® Hydrophilic Vinyl Polysiloxane Impression Material, but has many properties of a polyether like Polyjel® NF™ Elastic polyether Impression Material. The material stays in the tray, but also flows well from a syringe. The hydrophilic nature allows complete and accurate reproduction of supra and subgingival regions.

Hydrosil® 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 Hydrosil® Impression Material is at the discretion and sole responsibility of the dental practitioner.

COMPOSITION

Polydimethylsiloxane polymer
Calcium Sulfate
Silicon Dioxide
Polymethylhydrogen Siloxane
Surfactant
Plasticizer
Pigments

INDICATION FOR USE

Hydrosil® Impression Material is suitable for:
All tooth, implant (closed flap) or tissue impression techniques where a light body (wash) and/or medium body (tray) material would be desired by the operator.

1. Single phase, one-step full arch, quadrant arch or double arch impression technique.
2. Edentulous and abutment/tissue overdenture impression with properly fitted tray.
3. Single phase (Monophase) for the duplication of models.

TECHNICAL DATA

ISO 4823	Type 2: Medium-bodied consistency
Mix Time	30-45 seconds
Working Time (22°C/72°F)	2'30"-3'30"
(room temperature mixing and preparation)	
Working Time (37°C/98°F)	Maximum 2'30"
(intraoral syringing prior to tray insertion)	
% Recovery from deformation	99.0% minimum
% Strain in compression	2.0% maximum
Detail Reproduction	< 20µ
Linear dimension change	< 0.5%

ADDITIONAL INFORMATION

Maximum intraoral Working Time	2'30" from start of syringing
(tray insertion time)	
Setting Time (Mouth Removal Time)	6 minutes from start of mix
Mixing ratio by volume	1 part base to 1 part catalyst

Data on file.

CONTRAINDICATIONS

None known.

WARNINGS

1. Avoid prolonged or repeated exposure of the Hydrosil® 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. Do not take internally.
   Eye & 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 Hydrosil® 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. Insufficient data exist to support the use of Hydrosil® Impression Materials for impressions on exposed bone. Hydrosil® Material should only be used on or around intact mucosa.
3. Allow Hydrosil® Impression Material to reach room temperature prior to use. Higher temperatures reduce work times and laboratory bench set times (faster), lower temperatures increase them (slower). Clinically, intraoral set time (Mouth Removal Time) is unaffected within the range of allowable storage and initial mixing temperatures.
4. Never interchange different lots of Hydrosil® Impression Material base and catalyst. Unpredictable work and/or set times may result.
5. 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).
6. Close tubes immediately after use. Do not interchange base and catalyst screw caps.
7. Hydrosil® Impression Material should be used with suitable impression trays pre-treated with Tray Adhesive. *(See Step-by-Step Instructions)*

STORAGE

Store Hydrosil® Impression Material in tightly closed original tubes at or below room temperature (25°C/77°F). Refrigerated storage is acceptable when not in use. Allow material to reach 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)*

INTERACTIONS

1. Hydrosil® Impression Material should not be intermixed with, or used in conjunction with, other manufacturer's vinyl polysiloxanes. Hydrosil® Impression Material should not be intermixed with, or used in conjunction with, polyether, polysulfide or conventional (condensation cured) silicones.
2. Do not contaminate retraction cords with latex of "sulfur-containing" polymeric gloves. Handle cords with college pliers. Do not touch prepared tooth with gloves.
3. Use of some hand soaps and lotions can lead to interference with the 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.
4. If the preparation is treated with hydrogen peroxide, rinse with copious amounts of water before making the impression.

STEP-BY-STEP INSTRUCTIONS

1. **Crown and Bridge Impressions** – Single Phase One-Step Technique
   Technique Tip: It is highly recommended to utilize an assistant to assure 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. Caulk First Bite® Impression Trays are indicated for the impression of one or two teeth prepared for crowns, inlays or onlays while simultaneously recording the opposing dentition and bite registration of the two arches.
   1.2 Brush a thin layer of tray adhesive onto tray following the tray adhesive manufacturer's *Directions for Use.* The tray adhesive should be used even with perforated trays.
   1.3 If there is any debris or blood, clean the field with air water spray. Remove excess water with suction. Do not desiccate the tooth. Dry and isolate with cotton rolls.
   1.4 Extrude equal lengths of catalyst and base onto mixing pad.
   1.5 Using a stiff spatula and a stropping action, mix impression material, load syringe and tray (assistant). To obtain optimum physical properties, the mix should be completely homogenous (streak-free). Do not exceed 45 seconds of mixing.
   1.6 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. Do not blast with air. Hydrosil® Material's hydrophilic properties improve adaptation to the tooth enabling better "wetting".

1.7 Seat loaded tray. Tray must be inserted within 2'30" from time of first syringing of wash material intraorally.

1.8 Retain impression in position until firmly set. It sets more promptly in the mouth than on the bench. Be sure it is firm, resilient and non-tacky before removal. Minimum removal time is 6 minutes from start of mix. At 72°F (22°C) Hydrosil® Material has a minimum work time of 2 minutes 30 seconds. At 98°F (37°C) Hydrosil® Material has a maximum intraoral work time of 2'30". Variations in temperature from that stated above will affect work and set times. Higher temperatures reduce work times and lower temperatures increase them.

1.9 Remove impression by pulling slowly to break seal, then snap out along the long axis of the tooth. Rinse impression under cold water and blow dry.

2. **Edentulous/Overdenture Impression Technique**

2.1 Prepare a suitable tray with proper border extensions. Higher viscosities of Aquasil Ultra or Reprosil® Material may be used for border molding *(see complete Directions for Use).* Alternatively, see complete *Directions for Use* for other selected border molding material.

2.2 The final impression can be made with Hydrosil® Impression Material. Apply Tray Adhesive to tray, avoiding placement on material forming borders, according to tray adhesive manufacturer's *Directions for Use.*

2.3 Dispense, mix, and load Hydrosil® Material onto the impression tray as outlined in Section 1. Do not layer the material or place it into rows. This technique ensures the least amount of air incorporation.

2.4 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 is 6 minutes from the start of mix. At 72°F (22°C) Hydrosil® Impression Material has a minimum work time of 2 minutes 30 seconds. Variations in temperature from that stated above will affect work and set times. **Higher temperatures reduce work times and lower temperatures increase them.**

2.5 Remove impression by pulling slowly to break seal, then snap out of the mouth. Rinse impression under cold water and air dry.

3. **Duplication of Models**

3.1 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.

3.2 Brush a thin layer of tray adhesive onto the tray following the manufacturer's *Directions for Use.*

3.3 Dispense, mix and load the impression tray with Hydrosil® Material as described above. Do not layer the material or place it into rows. This technique ensures the least amount of air incorporation.

3.4 It is suggested to simultaneously syringe, using Hydrosil® Impression Material, completely around the model teeth, making sure to keep tip within impression material. Inject syringe material into any existing anatomy and continue syringing around the teeth until they are completely covered with syringe material.

3.5 Seat model into the loaded tray. Retain impression in position until firmly set. **(NOTE:** The material sets slower on the bench that in the mouth.) Check impression to be sure it is firm, resilient, and non-tacky before removal. The Minimum Removal time is 6 minutes from the start of mix. At 72°F (22°C) Hydrosil® Impression Material has a minimum work time of 2 minutes and 15 seconds. Variations in temperature from that stated above will affect work and set time. Higher temperatures reduce work times and lower temperatures increase them.

3.6 Remove model from impression by pulling slowly to break seal.

CLEANING AND DISINFECTION

Cleaning Instructions

The tightly closed tubes may be cleaned by wiping with a towel soaked with hot water and soap or detergent. Tubes should be wiped, not immersed. Tubes 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.

Technique Tip: Unset Hydrosil® 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 tubes
   - Expiration date

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