Aquasil Ultra Cordless

Tissue Managing Impression System

- Aquasil Ultra Cordless Tissue Managing Wash and Tray Impression Material
- For use with digit power™ Dispenser
- In digit power™ Single and Multi Cartridges
- Used with integrated mixing and intrasulcular tip

DIRECTIONS FOR USE - ENGLISH

Caution: For dental use only.
U.S.A.: Rx only.

1. PRODUCT DESCRIPTION
Aquasil Ultra Cordless Tissue Managing Impression Material is a quadrufunctional hydrophilic addition reaction silicone, elastomeric impression material. Aquasil Ultra Cordless Wash Impression Material in digit power™ Single and Multi cartridges is designed to be placed directly into the gingival sulcus using the digit power™ Dispenser and integrated mixing and intrasulcular tip to capture subgingival preparation detail without manipulating the surrounding soft tissue.

Without the need for retraction cords, techniques or materials, the Aquasil Ultra Cordless Impression System increases patient comfort, reduces procedure time and captures undistorted gingival tissue position. Aquasil Ultra Cordless Impression Material with Smart Wetting™ improves both wetting on the tooth surface and model detail reproduction.

1.1 Delivery forms*
Aquasil Ultra Cordless Tissue Managing Impression Material is available in:
- Wash Impression Material
  - unit dose digit power™ Dispenser Cartridges
  - Single (0.7mL) size, for one preparation only; 3’00’’ Mouth Removal Time when used with Aquasil Ultra Cordless Tray Material
  - Multi (1.6mL) size, for up to four preparations; 4’30’’ Mouth Removal Time when used with Aquasil Ultra Cordless Tray Material

- Tray Impression Material
  - 50mL Cartridges
  - 5:1 DECA™ delivery for Dynamic Mixing Machines

*Some delivery forms may not be available in all countries

1.2 Composition
Aquasil Ultra Cordless Tissue Managing Impression Material
Polydimethylsiloxane polymer; Polymethylhydrogen Siloxane; Silicon Dioxide; Sodium Aluminosilicate; Organic Platinum Complex; Surfactant; Titanium Dioxide; Metallic Oxide Pigments; Sodium aluminosulfosilicate; Fluorescent pigments; FD&C Blue #1; Peppermint Oil

1.3 Indications for use
Aquasil Ultra Cordless Tissue Managing Impression System is suitable for:
- Single or multiple preparation impression technique where subgingival placement of light body (wash) material would be desired by the operator.
- Dual phase, one-step (“double-mix”) impression technique, Aquasil Ultra Cordless Wash (Single or Multi) with Aquasil Ultra Cordless Tray, scanable Impression Materials.

1.4 Contraindications
Aquasil Ultra Cordless Tissue Managing Impression Material is contraindicated for use with patients who have a known hypersensitivity to peppermint oil or any of the components

1.5 Technical specifications
Classification:
- Wash: ISO 4823, Type 3, Light-Bodied Consistency
- Tray: ISO 4823, Type 2, Medium-Bodied Consistency

Working Time:
- Wash (37°C/98°F)...........................Single: 0’35’’ Maximum
  (introral syringing prior to tray insertion)........Multi: 1’00’’ Maximum
- Tray (22°C/72°F).............................1’00’’-1’15’’ (room temperature mixing and preparation, maximum insertion time)

Setting Time (Mouth Removal Time)..............Single: 3’00’’ from start of mix
  Multi: 4’30’’ from start of mix

- % Linear Dimensional Change ..................< 0.50
- % Recovery from deformation ..................98
- Detail Reproduction ................................20 microns

1.6 Compatible tray adhesive
Aquasil Ultra Cordless Tissue Managing Impression Material is compatible with conventional tray adhesives designed for use with vinyl polysiloxane materials (see complete Directions for Use).

2. GENERAL SAFETY NOTES
Be aware of the following general safety notes and the special safety notes in other chapters of these directions.

Safety alert symbol
This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.

2.1 Warnings
1. Aquasil Ultra Cordless Tissue Managing Impression Material contains polymerizable monomers and surfactants which may be irritating to skin, eyes and oral mucosa and may cause allergic contact dermatitis in susceptible persons.
  - Avoid eye contact to prevent irritation and possible corneal damage. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
  - Avoid skin contact to prevent irritation and possible allergic response. In case of contact, reddish rashes may be seen on the skin. If contact with skin occurs immediately remove material with cotton and wash thoroughly with soap and water. In case of skin sensitization or rash, discontinue use and seek medical attention.
  - Avoid ingestion/swallowing of material to prevent irritation or obstruction. 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.
  - Do not use Aquasil Ultra Cordless Tissue Managing 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.
  - Avoid multiple impressions at one sitting (more than three of the same arch/area) to prevent irritation to the oral mucosa. If symptoms occur discontinue use immediately. If irritation does not subside consult a physician.
  - Avoid use on periodontally involved teeth or teeth with compromised attachments, severe underlying or open fissions to prevent injury to periodontal tissues or tooth extraction.
  - Do not use excessive force to remove impression. If necessary, section tray and material for removal. Aquasil Ultra Cordless Tissue Managing Impression Material, formulated with high resistance to tearing, will typically not tear in the sulcus, and may become trapped in deep pockets or furcations. Always check sulcus after procedure and rinse thoroughly with water after procedure.

2. Care should be taken to have good control on any instrument to protect patients from injury. Do not use excessive force when inserting digit power™ intrasulcular tip into the gingival sulcus, if injury occurs, thoroughly wash the affected area with water and seek appropriate medical attention.

3. Used digit power™ intrasulcular tips are contaminated and sharp. Following use of digit power™ intrasulcular tips, proper handling and disposal techniques are required.
  - Follow proper exposure control plans. In the event of an accidental exposure, follow recommended post-exposure procedures. For digit power™ Dispenser see Hygiene section at the end of these directions.
  - When handling or disposing, use precautions as when handling or disposing other contaminated sharps.

4. Use only digit power™ cartridges containing Aquasil Ultra Cordless Tissue Managing Wash Material in the digit power™ Dispenser. Use of other cartridges and/or materials may lead to cartridge rupture, material incompatibility and/or failed impressions.

2.2 Precautions
- 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.
  - Insufficient data exist to support the use of Aquasil Ultra Cordless system for impressions on exposed bone. Aquasil Ultra Cordless system should only be used on or around intact mucosa.
  - Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
  - Devices marked “single use” on the labeling are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination.
  - Avoid placing excessive pressure in an apical direction on the intrasulcular tip when placing into sulcus or when dispensing material. Apical force may result in injury to periodontal tissues. (See Warnings)
  - All products should be used at room temperature. Higher temperatures reduce work times and laboratory bench set times (faster), lower temperatures increase them (slower).
  - To obtain optimum physical properties, the mix should be completely homogeneous (streak free).
AquaSil Ultra Cordless Tissue Managing Impression Material should be used with properly fitted, rigid trays for most applications. Trays with retentive features such as DENTSPLY Caulk Rim-Lock™ Trays or perforations, pretreated with tray adhesive, are recommended. To reduce gaging, choking or swallowing, do not overfill tray. 

AquaSil Ultra Cordless Tissue Managing Impression System performance is influenced by preparation design and gingival health. Preparations should have clearly defined finish lines. Gingival tissue should be healthy, with adequate hemostasis established. Uncontrolled fluid or bleeding management or ill-defined preparation finish lines may lead to impression inadequacy and ill-fitting restorations.

Interactions:
• Do not use Hydrogen peroxide-containing dental materials in conjunction with this product since they may interfere with the hardening of the polymeric components.
• Use of latex or “sulfur-containing” polymeric gloves, 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 use will avoid this possibility.
• AquaSil Ultra Cordless Tissue Managing Impression Material should not be intermixed with, or used in conjunction with, other manufacturer’s vinyl polysiloxanes or any polyester, polysulfide or conventional (condensation cured) silicones.
• The dual phase, two-step (“putty/wash”) crown and bridge impression technique is not recommended with the AquaSil Ultra Cordless System.

2.3 Adverse reactions
• Eye contact: irritation and possible corneal damage.
• Skin contact: irritation or possible allergic response. Reddish rashes may be seen on the skin.
• Bowel obstruction or other digestive distress may result from ingestion of mixed impression material. (See Warnings)
• Product misuse may cause injury to periodontal tissues and/or teeth. (See Warnings and Precautions)
• Failure to properly employ accepted handling and disposal techniques may present biohazard. (See Warnings)

2.4 Storage conditions
Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.
• Store at temperatures between 10°C/50°F - 24°C/75°F.
• Use the product at room temperature.
• Do not store used cartridges with new (unused) mixing tips attached.
• Do not freeze.
• Protect from moisture.
• Do not use after expiration date.

3. STEP-BY-STEP INSTRUCTIONS
3.1 Digital power™ Dispenser
Install Dispenser onto delivery unit according to the Operation Manual available separately.
• The Regulator speed control knob has four dispensing speed settings with 1 being the slowest and 4 being the fastest. The dispensing speed can also be set between numbers depending on your preference.
• Start out using the slowest speed setting and adjust upward as desired after becoming familiar with the technique.
• Check the pressure before each use and never bypass the Regulator.

3.2 Cartridge dispensing gun
1. Insert cartridge into dispensing gun.
2. Bleed cartridge before installing new mixing tip.
3. Disinfect cartridge dispensing gun, cartridge and attached used mixing tip for storage.
• Immediately prior to subsequent usage, remove the used mixing tip, bleed cartridge, install a new mixing tip.
• Dispose of cartridge when empty. Do not attempt to refill or consolidate used cartridges.

3.3 DECA™ cartridge loading
NOTE: Heavy Cartridge: Dropping may result in damage to the cartridge rendering it unusable. The DECA™ cartridge fits duomix, Pentamix™, MixStar, Dynamix and Volume Mix dynamic mixers. Carefully remove dispensing cartridge from the package. Also refer to separate dynamic mixer manufacturer's instructions.
1. Remove the cap from the cartridge.
2. Insert the cartridge into the dynamic mixer.
3. Bleed the cartridge before installing a new mixing tip.
4. Install a mixing tip. Use only DENTSPLY mixing tips. Other tips may not seal properly.
5. Place locking ring over the mixing tip and turn until ring is locked in place.
6. Dispense the mixed base and catalyst into a suitable tray.
• Immediately prior to subsequent usage, remove the used mixing tip, bleed cartridge, install a new mixing tip.

3.4 Loading and using the digital power™ Dispenser
To test functionality pre-operative, please follow directions below, extruding one cartridge, prior to use on patients.
• Prepare a digital power™ Dispenser Single or Multi cartridge for use by snapping the circular disk off the cartridge. Insert unit dose cartridge into mixing tip. Ensure both cartridge spurs fully lock into the square holes on the side of the mixing tip. Use only the provided digital power™ mixing tips with preassembled intrasulcular tips.
• Remove the Cap from the Dispenser and insert the digital power™ cartridge mixing tip assembly into the Cap.
• Lock the Cap onto the Dispenser with a ¼ clockwise turn until the alignment notches line up.
• To reduce Dispenser contamination, placing a digital power™ protective barrier sleeve over Dispenser is recommended.

3.5 AquaSil Ultra Cordless Tissue Managing Impression Technique: Dual Phase one-step (“double-mix”) Technique with a Rigid Tray or with Dual Arch Technique. NOTE: Tray and wash material mix timing: It is highly recommended to utilize an assistant to assure simultaneous syringing and tray loading.

CAUTION
Failure to properly employ accepted handling and disposal techniques may present biohazard. (See Warnings)

Blood and Fluid Control
• Do not use Hydrogen peroxide-containing dental materials in conjunction with this product since they may interfere with the hardening of the polymeric components.
• Product misuse may cause injury to periodontal tissues and/or teeth. (See Warnings and Precautions)
• Eye contact: irritation and possible corneal damage.

Periodontal tissue or tooth injury
• Do not inject AquaSil Ultra Cordless Tissue Managing Impression material into sulcus of periodontally involved teeth. Removal may be difficult.
• Injury may occur to teeth with open furcations or compromised periodontal attachment.
• Select other material or impression technique.

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• Select other material or impression technique.
• Depress the foot pedal to begin the flow of material. Material should flood the sulcus.
• Dispensing material ahead of the intrasulcular tip, gently move the intrasulcular tip completely around the preparation margin. Do not lift the intrasulcular tip out of the sulcus to minimize air entrapment.
• Once the sulcus is completely filled, with the foot pedal still depressed and material flowing, gently withdraw the intrasulcular tip, continuing to dispense material completely around the preparation.
• For single preparations (Single cartridge): Entire cartridge may be dispensed onto the single preparation. Tray must be seated immediately upon completion of dispensing.
• For multiple preparations (Multi cartridge): Move intrasulcular tip to subsequent preparation(s) and repeat, covering at least the gingival 1/3 of each preparation to be impressed. The entire cartridge may not be dispensed. Tray must be seated immediately upon completion of dispensing.

NOTE: Tray and wash material insertion timing
Single: Loaded tray must be inserted within 35 seconds from time of first syringing of AquaSil Ultra Cordless Tissue Managing Single Wash Material intraorally.
Multi: Loaded tray must be inserted within 1 minute from time of first syringing of AquaSil Ultra Cordless Tissue Managing Multi Wash Material intraorally.

Timing Guide

<table>
<thead>
<tr>
<th>Time</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0:00 (0sec)</td>
<td>Begin simultaneous syringing and tray loading</td>
</tr>
<tr>
<td>Single: Up to 0:35” (35sec)</td>
<td>Complete syringing and seat loaded tray</td>
</tr>
<tr>
<td>Multi: Up to 1:00” (1min)</td>
<td>Remove set impression</td>
</tr>
<tr>
<td>Single: 3:00” (3min)</td>
<td>Remove set impression</td>
</tr>
<tr>
<td>Multi: 4:30” (4min 30sec)</td>
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4. HYGIENE

Cross-contamination
• Do not reuse single use products. Dispose in accordance with local regulations.
• Reprocess reusable products as described below.

4.1 Cleaning the digital power™ Dispenser and Cartridge Dispensing Gun
Remove protective barrier and discard. The digital power™ Dispenser and cartridge dispensing gun may be cleaned by scrubbing with a towel soaked with hot water and soap or detergent. Do not allow solution to penetrate the casing. To clean digital power™ Dispenser, remove Cap and depress foot pedal to advance plungers. Excess material may be cleaned with alcohol-moistened gauze. Refer to Dynamic Mixer manufacturer’s instructions for Dispenser cleaning and disinfecting instructions.
4.2 Disinfection of the digit power™ Dispenser and Cartridge Dispensing Gun
Disinfect Dispenser(s) and tips left in place on cartridges for storage with a hospital-level tuberculocidal disinfectant according to national and local regulations.  
• Sodium hypochlorite (0.525%), water based dual phenolics, alcohol based dual phenolics, and dual or synergized quaternary ammoniums are approved disinfectants.
• Use impregnated wipes not sprays. Do not immerse the Dispenser in disinfectant. The disinfectant manufacturer’s directions should be followed properly for optimum results.

NOTE: Vigorous wiping can destroy the label. Wipe cartridge gently. Some phenolic based agents and iodophor based products may cause surface staining.

The digit power™ Dispenser blue plastic components – Cap, Grip and Adapter – can be steam autoclaved, at 132°C for a minimum of 5 minutes (unwrapped). Cap, Grip and Adapter may be autoclaved at least 200 times. Use of other sterilization procedures/methods is at the discretion and sole responsibility of the practitioner.

Technique Tip: Unset Aquasil Ultra Cordless Tissue Managing Impression Material can be removed from clothing with dry cleaning solvent.

4.3 Disinfection of the impression material
The impression should be disinfected with a hospital-level tuberculocidal disinfectant according to national and local regulations.  
• Iodophors, sodium hypochlorite (0.525%), chlorine dioxide, and dual or synergized quaternary ammoniums are approved disinfectants.
• Thoroughly soak by spraying or immerse the impression in any recommended hospital level disinfectant for the contact time recommended by the disinfectant manufacturer for optimum results.
• Water-based disinfectant solutions are preferred.

4.4 Casting
• The impression should be removed from the disinfectant, rinsed with water and lightly air dried.
• The impression may be poured in plaster or stone 30 minutes after disinfection or delayed up to fourteen days. For epoxy dies, delay pour 60 minutes.
• 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 dental plasters and die stones. Impressions may be silver or copper-plated.
• Aquasil Ultra Cordless Tissue Managing Impression Material may be scanned by dental scanning units designed for digital CAD/CAM procedures.

5. 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
   • Expiration date