

Algin•X™ Ultra

DENTSPLY

Alginate Alternative

DIRECTIONS FOR USE – ENGLISH

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

1. PRODUCT DESCRIPTION

Algin•X™ Ultra Alginate Alternative is an elastomeric dental impression material designed for making dental impressions that are classically made with standard alginate impression material. The use of Algin•X™ Ultra Material instead of traditional alginate material allows immediate pouring in the office following disinfection, or the option of delayed and/or repeated pours, without sacrificing accuracy, either in the office, or shipped to an off-site laboratory.

1.1 Delivery forms

Algin•X™ Ultra Material is available in:

- 50mL cartridges for dispensing gun
- 380 ml DECA™ cartridges for dynamic mixing machines

1.2 Composition

Polydimethylsiloxane polymer; Polymethylhydrogen Siloxane; Silicon Dioxide; Sodium Aluminosilicate; Organic Platinum Complex; Surfactant; Titanium Dioxide; Sodium Aluminosulfosilicate Pigment; FD & C Blue #1 Pigment; Spearmint Oil

1.3 Indications for use

Algin•X™ Ultra Material is indicated for making dental impressions for:

- study models
- orthodontic models
- counter impressions
- partial denture impressions
- temporary crown fabrication

1.4 Contraindications

None known.

1.5 Technical specifications

Classification: ISO 4823, Type 2, Medium-Bodied Consistency

Working Time (22°C/72°F) 1'00" (room temperature mixing and preparation, maximum insertion time)

Setting Time (Mouth Removal Time) 2'30" from start of mix

% Strain-in-Compression 3-5

% Linear Dimensional Change < 0.50

% Recovery from deformation ≥ 98

Detail Reproduction 20 microns

1.6 Compatible tray adhesive

Algin•X™ Ultra Material is compatible with conventional tray adhesives such as Caulk® Tray Adhesive 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.

2.1 Warnings

1. Algin•X™ Ultra 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 Algin•X™ Ultra 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.

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 Algin•X™ Ultra Material for impressions on exposed bone. Algin•X™ Ultra Material should only be used on or around intact mucosa.

• 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).

• Algin•X™ Ultra Material should be used with properly fitted, rigid trays with sides, for most applications. Trays with retentive features such as Caulk Rim-Lock® Trays or perforations, pretreated with tray adhesive, are recommended. To reduce gagging, choking or swallowing, do not overfill tray.

• Material should extrude easily; DO NOT USE EXCESSIVE FORCE. Excessive pressure may result in unanticipated extrusion of the material or cause cartridge rupture.

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.

• Algin•X™ Ultra Material should not be intermixed with, or used in conjunction with, other manufacturer's vinyl polysiloxanes or any polyether, polysulfide or conventional (condensation cured) silicones.

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)

2.4 Storage conditions

Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.

• Store at temperatures between 2°C/35°F - 24°C/75°F.

• Refrigerated storage is acceptable when not in use.

• Use the product at room temperature. Allow sufficient warm-up time if product was stored in a refrigerator.

• Do not freeze.

• Protect from moisture.

• Do not use after expiration date.

3. STEP BY STEP INSTRUCTIONS

3.1 Cartridge dispensing gun

1. Insert cartridge into dispensing gun.

2. Remove the cartridge cap or used mixing tip.

3. Bleed cartridge before installing new mixing tip.

4. Install a new mixing tip on the cartridge.

5. Squeeze dispenser trigger with moderate and even pressure to begin mixing material. Material will stop flowing after trigger is released.

6. Disinfect cartridge dispensing gun, cartridge and attached used mix tip for storage.

- Immediately prior to subsequent usage, remove the used mixing tip and squeeze the dispensing gun trigger to dispense (bleed) material from the two openings of cartridge. Wipe end of cartridge. Install a new mixing tip.
- To remove the cartridge, hold the release lever vertically while simultaneously withdrawing plunger in a backward direction. Dispose of cartridge when empty. Do not attempt to refill or consolidate used cartridges.

3.2 DECA™ cartridge loading

NOTE: Heavy Cartridge. Dropping may result in damage to the cartridge rendering it unusable.

The DECA™ Cartridge fits Duomix™, all Pentamix® models, MixStar, Dynamix and Volume Mix dynamic mixers. Carefully remove dispensing cartridge from the package.

DECA™ Cartridge Loading: Also refer to separate dynamic mixer manufacturer's instructions.

1. Carefully remove dispensing cartridge from the package.

2. Hold the cartridge with dispensing nozzles up.

3. Grasp the tab on the cap with thumb and forefinger and remove the cap from the cartridge.

4. Insert the cartridge into the dynamic mixer according to the directions supplied by the manufacturer.

5. Activate the dispense control to bleed the two nozzles of the cartridge before installing a new mixing tip.

6. Install a supplied mixing tip on the cartridge following the machine manufacturer's directions. Use only provided mixing tips. Other tips may not seal properly.

7. Be sure the internal central hex of the dynamic mixing tip is aligned correctly with the drive shaft of the dynamic mixer.

8. Once the mixing tip is properly placed, place nozzle locking ring over the mixing tip and turn to the right (1/4 turn) until ring is locked in place.

9. Dispense the mixed base and catalyst into a suitable tray.

10. Immediately after dispensing, back the plungers of the machine off to reduce excess material flowing from the tip.

11. After disinfection, keep the used mixing tip in place until the next use to serve as a self-sealing cap.

- Immediately prior to subsequent usage, remove the used mixing tip and activate the dispensing mechanism to dispense (bleed) material from the two openings of cartridge. Wipe end of cartridge. Install a new mixing tip.

Impression Technique

1. Dispense Algin•X™ Ultra Material directly into impression tray. Do not overfill tray.

2. Insert filled tray into the mouth. Tray must be seated within **1 minute** from the start of mixing. Press tray gently into position. Do not overseat tray. Immediately muscle trim. Remove undesired excess beyond tray, e.g., retromolar areas.

3. 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 **2 minutes 30 seconds** from the start of mix.

4. Remove impression by pulling slowly to break seal, then snap out along the long axis of the teeth. Have patient rinse with warm water. Check for and remove residual material from mouth and/or between teeth.

5. Rinse impression thoroughly under running water. Follow disinfection procedures below before shipping and/or pouring.

4. HYGIENE

4.1 Cleaning the dispenser

The cartridge dispensing guns may be cleaned by scrubbing with hot water and soap or detergent. Excess material may be cleaned with alcohol-moistened gauze.

4.2 Disinfection of the dispenser and cartridge

Disinfect dispensers, cartridges and used tips left in place on cartridges for storage with a hospital-level tuberculocidal disinfectant according to national and local regulations. Use impregnated wipes not sprays. **NOTE:** Destruction of the label by vigorous wiping. Wipe cartridge gently.

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 dispenser and plunger. The disinfectant manufacturer's directions should be followed properly for optimum results.

Technique Tip: Unset Algin•X™ 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 (5.25%), chlorine dioxide, and dual or synergized quaternary ammoniums are approved disinfectants.
- To disinfect poly(vinyl siloxane) material, 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 immediately or delayed up to fourteen 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 dental plasters and die stones.

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 on the cartridge
- Expiration date

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