

Jeltrate® Plus™

Regular Set and Fast Set Antimicrobial Dustless Alginate Impression Material

DIRECTIONS FOR USE – ENGLISH

Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material is an irreversible hydrocolloid material designed for making dental impressions for case study models, orthodontic models, and opposing models. Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material is also suitable for use in the fabrication of casts for most removable partial denture frameworks, removable orthodontic and removable occlusal splint appliances, mouthguards and custom trays.

Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material contains an antimicrobial agent to reduce chances of cross contamination after 15 seconds of water rinsing prior to disinfection, and is formulated to reduce airborne particles when dispensing and mixing. Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material is available in 10,000g bulk containers, 454g canisters and 25g single pouches.

Bulk Container Contents:	625 Two-Scoop Average impressions 416 Three Scoop Large Impressions
Single Container Contents:	28 Two-Scoop Average Impressions 18 Three-Scoop Large Impressions
Single Pouch Contents:	1 Three-Scoop Large Impression

ADA SPECIFICATION 18

Mix Ratio: FAST SET: 8 g Average; REGULAR SET: 8g Average: 19 mL water

ISO SPECIFICATION 1563-1990

	FAST SET	REGULAR SET
Mixing Time	45 sec.	60 sec.
Total working time	1'30"	2'15"
Initial setting time	1'45"	2'30"
Setting time*	2'30"	3'30"

* Setting time includes mixing time and the minimum time for handling based upon mixing powder with distilled or deionized water at 23°C. The temperature and hardness (tap water) of the mixing water may vary the total working and setting time.

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

COMPOSITION

Crystalline Silica
Amorphous Silica
Calcium Sulfate
Tetrasodium Pyrophosphate
Potassium Alginate
Magnesium Oxide
Quaternary Ammonium Compound
Aspartame
Organic Glycol
D&C Red #30 (Fast Set)
Yellow Iron Oxide (Regular Set)

INDICATIONS

Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material is indicated for making dental impressions for the fabrication of casts for:

- case study models
- orthodontic models
- opposing models
- removable partial denture frameworks not involving transfers and/or precision attachments
- removable retainers and splints and provisional restorations.

CONTRAINDICATIONS

Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material must not be used with patients who have a history of severe allergic reaction to any of the components.

WARNINGS

1. (The following statement is required by the State of California). This product contains crystalline silica (airborne particles of respirable size) which is known by the State of California to cause cancer. Prior to use, read the Material Safety Data Sheet (MSDS) information and product instructions.
2. Jeltrate® Plus™ Antimicrobial Dustless Alginate contains crystalline silica. Avoid prolonged exposure to eyes. Avoid prolonged inhalation. Do not take internally. Mix water and powder carefully to minimize dust inhalation risk and decrease airborne particles to exposed individuals.
Eye contact: Before using this product wear protective glasses as well as covering the patient's eyes to protect from contact. In case of contact with eyes, flush eyes with copious amounts of water for 15 minutes. If irritation persists, seek medical attention.
Inhalation: In case of inhalation, move subject to fresh air. Drink water to clear throat and blow nose to evacuate material. If irritation or soreness persists, seek medical attention.
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.
3. Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material contains aspartame and should not be used with patients who have a history of phenylalanine metabolic disorder. In the event of exposure, PKU patients that are or may be pregnant should seek medical advice.
4. Patients should wear protective eyewear. Dental professionals should wear protective eyewear, mask, gloves and clothing while using Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material.
5. Making multiple impressions at one sitting (more than three of the same arch/area) may cause mucosal irritation. If irritation persists, discontinue use and seek medical attention.
6. Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material contains coloring agents and should not be used with patients who have a history of severe allergic reaction to them (*see Contraindications*). In the event of allergic reaction, seek immediate medical attention.

PRECAUTIONS

1. This product is intended to be used 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. Do not expose material to, or use in conjunction with hydrofluoric acid. Exposure of the silica contained within Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material to hydrofluoric acid renders the product unstable.
3. Use in a well-ventilated area. Avoid inhaling airborne particulates. *See Warnings*
4. Replace original canister lid tightly immediately after dispensing.
5. The temperature and hardness of the water used for mixing will affect the work time and set time. Recommended water temperature is 23°C/73°F. *See Step-by-Step Instructions*
6. Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material is not recommended for transfer impressions or final impressions for fixed restorations.
7. Impressions should be cast immediately (upon completion of disinfection) in a suitable gypsum material. Do not store impressions submersed in water. Do not package and ship impressions for remote pouring/casting.
8. Prior to each use, fluff powder before dispensing by gently tumbling tightly closed canister.
9. **Storage:** Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material should be stored in its original container with the lid (and bag, for bulk container) tightly closed. Store out of direct sunlight, in a well-ventilated place at temperature not to exceed 29°C/85°F. Prolonged heat greater than 60°C (140°F) makes the product unstable. Do not allow exposure to moisture or excessive humidity. High humidity and water contamination will cause material to gel. Do not use after expiration date. Store clean, dry, properly disinfected plastic water and powder measures at room temperature. Do not store scoop and/or cup in the canister containing Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material.

ADVERSE REACTIONS

1. Product may cause serious health effects if inhaled. Inhalation of crystalline silica has been classified as carcinogenic. Inhalation of powder may cause varying degrees of damage to the affected tissue and also increased susceptibility to respiratory illness. *See Warnings, Precautions*
2. Product contains aspartame, and may cause hyperphenylalaninemia in susceptible individuals. Hyperphenylalaninemia may have harmful effects on developing fetus. *See Warnings*
3. Product may irritate the eyes and skin. **Eye contact:** irritation and possible corneal damage. **Skin contact:** irritation or possible allergic response. Reddish rashes may be seen on the skin. **Mucous Membranes:** inflammation, edema, sloughing. *See Contraindications, Warnings*
4. The following medical conditions are generally aggravated by exposure: Individuals with pre-existing upper respiratory and lung disorders, eye problems, phenylketonuria.

STEP-BY-STEP INSTRUCTIONS

1. **Initial Use (10,000g bulk container):** Transfer of smaller quantity material into clean, dry container (canister) is recommended. Stir bulk container contents prior to initial and subsequent transfers. Thereafter, follow steps 3-13.
2. **Initial Use (454g canister):** Prior to removing canister lid, carefully cut tape along the lid bottom. Thereafter, follow steps 3-13
3. Select and/or prepare a suitable impression tray. Rigid trays (with sides) are recommended for most applications. Trays with retentive features such as Caulk Rim-Lock® Trays or perforations are recommended. Commercially available alginate tray adhesive is not necessary with these trays, but may be used if desired following manufacturer's instructions.
4. **Before dispensing material:** For canister, tumble closed container gently to fluff powder. *See Warnings, Precautions*
5. Dip supplied (8g) scoop lightly into powder until the scoop is full. Do not pack scoop against container wall.
6. Tap scoop against rim to insure full measure without voids. Scrape excess off with a spatula to achieve level scoop. **Technique tip:** Tap spatula lightly on the filled scoop until the powder is fully condensed. Then scrape excess if necessary.
7. Empty the scoop into a clean, dry mixing bowl. Repeat steps 5 and 6 until the desired amount of powder is in the mixing bowl. For single use pouch, tear open pouch side and empty the entire pouch contents into the mixing bowl.
8. For each one (1) scoop (8g) of powder add 1/3 measure of water (19ml). For each two (2) scoops of powder add 2/3 measure of water. For each three (3) scoops of powder, or one single use pouch, add one (1) whole measure of water. For best results, use distilled water at approximately 73°F (23°C). **Technique tip:** Colder water retards setting; warmer water hastens setting.
9. Mix water and powder carefully at first, until all powder is wetted. Once all powder is incorporated, continue to spatulate in a vigorous fashion. Spatulate against the bowl sides to reduce air incorporation. Do not whip or stir material.
Technique tip: To produce a creamy mix, spatulate REGULAR SET Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material for 1 minute and FAST SET Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material for 45 seconds.
10. Once the material appears to be creamy but with consistency, apply the Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material onto the tray. To minimize air incorporation, wipe the loaded spatula against the tray rim, allowing material to flow from the spatula into the tray.
11. Insert filled tray into the mouth. Press tray gently into position. Do not overseat tray. Immediately muscle trim. Hold seated tray immovable for 1 minute after stickiness vanishes. When mixed with distilled water at 23°C, the set time of FAST SET Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material is approximately 2'30" from start of mix. The set time of REGULAR SET Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material is approximately 3'30" from start of mix.
12. Once material sets, break seal, snap and remove impression from mouth. Have patient rinse with warm water. Check for and remove residual material from mouth and/or between teeth.
13. Rinse impression thoroughly under running water. Immediately disinfect following disinfection procedures below before pouring. Impression should be poured immediately after disinfection, following casting procedures below. If later pouring is necessary, wrap impression in wet towel. DO NOT STORE IMPRESSION SUBMERGED IN WATER.

DISINFECTION OF THE IMPRESSION

The impression should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are those that are EPA-registered as tuberculocidal at a maximum contact time of 10 minutes. Iodophors, sodium hypochlorite (5.25%), chlorine dioxide, dual or synergized quaternary ammonium compounds are approved disinfectants. To disinfect set impression material, thoroughly soak by spraying, then wrapping impression in plastic bag for the contact time recommended by the disinfectant manufacturer for optimum results, but not longer than 10 minutes. Spraying with glutaraldehyde is not recommended. Water-based disinfectant solutions are preferred.

CASTING

Following the recommended disinfectant contact time (maximum 10 minutes), the impression should be removed from the disinfectant, rinsed with water and lightly air dried. Pour impression, following gypsum manufacturer's directions, within one minute upon removal from the disinfectant and rinsing. If later pouring is necessary, wrap impression in wet towel and/or store at 100% humidity. Do not delay pour more than 24 hours. Impression distortion is proportional to the delay in pouring and amount of water evaporation.

The material is compatible with the following die stones:

ALPHA MODIFIED GYPSUM (Type IV)	Glastone®*
ALPHA MODIFIED GYPSUM	Alpha Dur 700 **
Alpha Gypsum (Type III)	Castone*
Alpha Gypsum	Calestone, E.P.1**

(*Products of DENTSPLY International Inc.) (**Not products of DENTSPLY International Inc.)

CLEANING AND DISINFECTION OF WATER AND POWDER MEASURES

The water (cup) measure and powder (scoop) measure may be cleaned by scrubbing with hot water and soap or detergent. The cup and/or scoop, if exposed spatter or spray of body fluids or that may have been touched by contaminated hands, or oral tissues, should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are EPA-registered as tuberculocidal. Disinfect the cup and/or scoop by spraying with any recommended hospital-level dual or synergized quaternary ammoniums or immersing in hospital-level disinfectant such as dual or synergized quaternaries or glutaraldehyde for the contact time recommended by the disinfectant manufacturer for optimum results. Spraying with glutaraldehyde is not recommended. Chlorine based (bleach), some phenolic-based agents and iodophor-based products should not be used as they may cause surface staining and/or color alteration. Agents containing organic solvents, such as alcohol, should be avoided, as they may tend to dissolve the plastic. Water-based disinfectant solutions are preferred. The disinfectant manufacturer's directions should be followed properly for optimum results.

Following disinfection, thoroughly rinse and dry the cup and/or scoop before storage. Autoclaving the cup or scoop is not recommended.

CLEANING AND DISINFECTION OF CANISTER

The canister may be cleaned by wiping with a disposable towel soaked with hot water. To prevent Jeltrate® Plus™ Antimicrobial Dustless Alginate Impression Material canister from exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended to avoid package contamination.

The canister, if exposed spatter or spray of body fluids or that may have been touched by contaminated hands, or oral tissues, should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are EPA-registered as tuberculocidal. Iodophors, sodium hypochlorite (5.25%), chlorine dioxide and dual or synergized quaternaries are approved disinfectants. Disinfect the canister (with lid tightly closed) by spraying the canister with any recommended hospital-level disinfectant except glutaraldehyde for the contact time recommended by the disinfectant manufacturer for optimum results. 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. Water-based disinfectant solutions are preferred.

LOT NUMBER AND EXPIRATION DATE

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

©2005 DENTSPLY International Inc. All Rights Reserved

Manufactured in the U.S.A. by:
DENTSPLY Caulk
38 West Clarke Ave.
Milford, DE 19963
1-302-422-4511

Distributed by:
DENTSPLY Canada
161 Vinyl Court
Woodbridge, Ontario
L4L 4A3 Canada

Authorized EU Representative
DENTSPLY DeTrey GmbH
De-Trey-Str. 1
78467 Konstanz
Germany
Tel. (49) (07531) 583-0

Swiss Representative
DENTSPLY DeTrey
Baar Office
Oberdorfstrasse 11
6324 Baar
Switzerland
Tel. (41) (041) 7662066