

Oral Bond™

Oral Bond™ is a sterile dental adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D and C Yellow #10. Oral Bond™ is a liquid of syrup-like viscosity and polymerizes in seconds. Oral Bond™ is supplied in a multiuse dispensing bottle.

INSTRUCTIONS:

CRITICAL: MUST BE KEPT IN FREEZER AT ALL TIMES UNTIL READY TO USE TO AVOID SETTING & LOSE THICKNESS OF VISCOSITY

Oral Bond™ must remain in the freezer until immediately prior to use. Prior to application of Oral Bond™, syringes can be loaded in the morning and kept in Freezer until ready to use later that day.

1. Squeeze desired amount of Oral Bond™ onto disposable dappen dish.
2. Using sterile syringe(s), withdraw Oral Bond™. Cap syringe and place back into freezer for later use that day.
3. Place protective eyewear on the patient prior to application.
4. Prior to applying Oral Bond™, remove needle from syringe and replace with black dispensing tip.
5. Oral Bond™ should be used immediately after placing the black dispensing tip on the syringe.
6. Thoroughly surround the materials being bonded by sterile gauze so all runoff is limited to the material being bonded.
7. Express a small amount of Oral Bond™ to assess the proper force to apply to the syringe plunger to avoid excessive application of Oral Bond™ in the oral cavity.
8. Express Oral Bond™ onto the area being bonded while ensuring that the tip of the applicator does not come in contact with materials. Allow Oral Bond™ to evenly flow over the area being bonded.
9. To help set Oral Bond™, spray water onto surface area where placed. Water helps set Oral Bond™.
10. Continue to monitor and isolate the material being bonded until complete polymerization of Oral Bond™ has occurred.

*To avoid premature setting of Oral Bond™:

Remove any excessive moisture from the materials being bonded. Moisture accelerates polymerization of Oral Bond™ and may affect bonding results.

Instruct the patient to avoid disturbing the bonded area and return in one to two weeks for removal of the bonded materials.

CONTACT INFORMATION

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Oral Bond™

INDICATIONS:

Oral Bond™ is indicated to be used as an adjunct to temporally assist in securing periodontal dressings.

HOW SUPPLIED: Oral Bond™ is supplied in multiuse vials with applicator tips and single use syringes.

STORAGE: Recommended storage conditions: store in a freezer

DO NOT USE AFTER EXPIRY DATE

WARNINGS AND PRECAUTIONS:

Oral Bond™ is a fast setting adhesive capable of adhering to most bodily tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.

Polymerization of Oral Bond™ adhesive may be accelerated by water, saliva or fluids containing alcohol.

It is advised that protective eyewear be provided to all patients to prevent Oral Bond™ coming in contact with the eyes. Care must be taken that Oral Bond™ does not come in contact with the cornea of the eye or into the conjunctival sac where it could cause adhesions. If contact with the eye occurs, flush the eye copiously with saline or water. If residual adhesive remains, apply typical ophthalmic ointment to help loosen the bond and contact and ophthalmologist.

CONTRAINDICATIONS:

Do not use in patients with a known hypersensitivity to cyanoacrylate or formaldehyde. Oral Bond™ must not come in contact with the conjunctival sac since conglutination may occur.

Federal Law restricts this device to sale by or on the order of a dentist.