

# Orthofix™ ADHESIVE

Orthodontic Adhesive - Light Cure Orthodontic Bonding System

## PRODUCT DESCRIPTION

Orthofix is designed for bonding metal and ceramic orthodontic brackets. Orthofix system contains light cure orthodontic adhesive in syringes and a primer. **ORTHOFIX ADHESIVE** is cured by exposing the material to visible light, at a wavelength of 400-500 nm (blue light) and an intensity of 500 mW/cm<sup>2</sup> for about 20 seconds.

## INTENDED USE / INDICATIONS FOR USE

**ORTHOFIX ADHESIVE** is used as a combined etchant and primer in orthodontic treatment with light curing direct bonding orthodontic adhesive. For bonding metal and ceramic orthodontic brackets.

## DIRECTIONS FOR USE

The ideal temperature for optimum handling property is between 18°C and 24°C. If refrigerated, make sure to bring the product to the above mentioned temperature atleast one hour before use.

### Tooth Preparation

- After scaling and oral prophylaxis, polish with oil-free pumice. Rinse with water. Isolate teeth with cheek retractor.
- Air dry thoroughly to leave the surface moisture-free.

### Etching

- Etch the teeth surfaces using *Eazetch* for 30 seconds.
- Rinse thoroughly with water for 1 minute.

### Priming with Orthofix Primer (Moisture Insensitive Primer)

- Place a few drops of *Orthofix Primer* in well.
- Using micro-tip brushes, apply a thin uniform coat of *Orthofix Primer* on each tooth surface to be bonded, and cure for 10 seconds at a wavelength of 400-500 nm (blue light) and an intensity of 500 mW/cm<sup>2</sup>.

### Bonding with Orthofix Light Cure Orthodontic Syringes

- Using the syringe, apply a desired quantity of **ORTHOFIX ADHESIVE** onto the base of the bracket. After applying, wipe the syringe tip and replace the cap.
- Immediately after applying the adhesive, place the bracket gently onto tooth surface.
- Set the bracket to its final position and press firmly.
- Gently remove any excess adhesive / flash from around the bracket base without disturbing the bracket.
- For bonding of metal brackets, apply and expose **ORTHOFIX ADHESIVE** for 20 seconds at a wavelength of 400-500 nm (blue light) and an intensity of 500 mW/cm<sup>2</sup>, approximately 2 mm above the interproximal contact. In order to achieve full curing of the bracket adhesive, both interproximal sides of the bracket must be cured.
- For bonding of ceramic brackets, apply and expose **ORTHOFIX ADHESIVE** for 10 seconds at a wavelength of 400-500 nm (blue light) and an intensity of 500 mW/cm<sup>2</sup> by placing the light source about 2 mm away from the bracket and shine the light through the ceramic bracket.
- Archwires can be placed immediately after bonding of the last bracket.

### Debonding

- Debond metal or ceramic brackets using a straight or curved debonding plier.
- Use a 12-fluted tungsten carbide bur in a gentle wiping motion with a low speed handpiece to remove any remaining adhesive from the tooth surface.
- After pumicing and polishing, apply topical fluoride as required.

## PRECAUTIONS

- It is advisable to wear an eyewear while handling **ORTHOFIX ADHESIVE**.
- ORTHOFIX ADHESIVE** contain acrylates which are found to cause allergic reactions in small percentage of population. To reduce the risk of allergic response, minimize exposure particularly to uncured resins. Use of protective gloves and no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If the adhesive contacts glove, remove and discard the glove, wash hand immediately with soap and water and then re-glove.
- Avoid contact with oral mucosa, eyes and skin. If accidental contact or irritation occurs, flush immediately with sufficient amount of water. In case of eye contact or irritation, please consult a physician.

## STORAGE

- Do not expose materials to elevated temperature or intense light.
- Do not store materials near eugenol-containing products.
- ORTHOFIX ADHESIVE** is to be stored between 10°C and 30°C. For maintaining the consistency of the product, it should be refrigerated when not in use.
- Make sure that **ORTHOFIX ADHESIVE** is always kept closed when not in use.

## SHELF LIFE

When stored between 10°C and 30°C, the product has a shelf life of 24 months from the month of manufacturing.












## PACKING / CONTENT

Each pack contains 1 syringe x 4 g (2.35 ml) and a pack insert.

## NOTE

The material is for the use of dental professionals only. Processing should be carried out strictly according to the instructions for use. Short light-cure exposure time (2-3 seconds) may not yield desired results. Liability cannot be accepted for damages resulting from misuse or failure to observe the instructions including storage conditions. The user is responsible for testing the product for its suitability and use for any other purpose that is not explicitly stated in the instructions.

## SYMBOLS

	Medical Device		Caution
	Lot No.		Manufactured by
	Instruction for Use		Date of Manufacture
	Storage Temperature		Date of Expiry
	Keep away from sunlight		Do not use if package is damaged
			Non Sterile

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