ENGLISH

INSTRUCTIONS FOR USE

CHAIRSIDE® Attachment Processing Material Normal Set and Attachment Processing Material Fast Set.

Indications

CHAIRSIDE® Attachment Processing Material is a dual-cure (either self-cure or UV light-cure) tissue colored composite material that is used to process attachments into full and partial dentures using either a chair-side or laboratory procedure. It may also be used to fill voids in a denture.

Advantages

- Auto mixing, delivered in a double barrel syringe
- Self-cure or accelerated cure with the application of UV light
- Low curing temperature
- The material bonds to itself to allow for easy void filling or addition of material
- Normal Set and Fast Set varieties available to match case complexity and desired procedure speed

Important – Special Instructions

Federal (USA) law restricts this device to sale by or on the order of a dentist or properly licensed practitioner.

The remote possibility always exists that a patient may have sensitivity towards CHAIRSIDE® Attachment Processing Material. Should an allergic reaction occur, use of the material must be avoided and an alternative material with different chemistry should be employed.

CHAIRSIDE® Attachment Processing Material is not affected by the MR environment and therefore has not been tested for heating or migration in the MR environment.

Single Use Device

The mixing tips of the CHAIRSIDE® Attachment Processing Material are for single use only. If re-used, Zest Anchors cannot guarantee the functionality nor the safety of the product. CHAIRSIDE® Attachment Processing Material cannot be dispensed properly with re-used mixing tips.

MULTI-USE DEVICES

Syringes and Cartridges are multi-use devices and are provided non-sterile. Use in accordance with instructions below.

Application

1. Denture Preparation: Being that CHAIRSIDE® Attachment Processing Material does not bond to another acrylic, an undercut in the denture is needed to provide maximum mechanical retention for the attachment in the denture.
2. CHAIRSIDE® Attachment Processing Material Preparation: Remove the end cap on the syringe or cartridge by turning ¼ turn counterclockwise and pulling. Discard the cap.

Note: The use of the 18 mL size CHAIRSIDE® Attachment Processing Material cartridge requires the use of a standard impression gun to dispense the material.

3. When using a syringe or cartridge for the first time, express material from the syringe or cartridge without a mixing tip in place until material is dispensed from both outlets.
4. Attach a new mixing tip by rotating the tip until it drops onto the syringe end and rotate ¼ turn clockwise to lock the tip in place. If it is desirable to utilize the Angled Tip, snap it onto the end of the mixing tip.
5. After attaching the mixing tip, extrude a small portion of material on to a mixing pad or other disposable surface. This will ensure the material in the tip is fully mixed.
6. Block out any undesired undercuts around the attachments, abutments or teeth.

Note: After the set time is reached, any undercuts that were not blocked out sufficiently may cause the denture to be locked

into place.

7. Dispense the ZEST CHAIRSIDE® Attachment Processing material. Apply a small amount of material around the attachment in the mouth or on the model. Dispense additional material into any recesses in the denture. The working time and setting time of the Normal Set and Fast Set materials are described in the table below. Working time is the amount of time available to seat the denture from the time the material is expressed from the tip. Setting time is the time from when the material is first mixed to the point the material is set sufficiently to retain the attachments. Cure Time is the earliest total time after which post processing and final seating can occur.

CHAIRSIDE® Attachment Processing Material	WORKING TIME At Room Temperature (73°F/23°C) min:sec	SETTING TIME At Room Temperature (73°F/23°C) min:sec	CURE TIME At Room Temperature (73°F/23°C) min:sec
Normal Set	1:45	5:00	7:00
Fast Set	0:30	2:00	3:00

8. Be sure to seat the denture passively, without excessive biting pressure. If the patient is allowed to displace the tissue by closing firmly, the attachments may be in the wrong position in the denture. This will make it difficult to seat the denture and have the attachments provide the proper retention.

Note: Removal prior to reaching the set time may allow the material to release from any unblocked undercuts; however, the attachments may not be retained in the denture, requiring the process to be repeated. The set time is established at room temperature. Use of the material at elevated temperature, such as in the oral environment, may shorten the set time.

9. The curing time may be accelerated by the application of UV light for 30 seconds.

Note: The cure time is established at room temperature. Use of the material at elevated temperature, such as in the oral environment, may shorten the cure time.

10. Excess material may be easily removed from areas of the denture using a dental bur.
11. In order to process an additional attachment into the denture or to fill voids in the denture, remove the mixing tip. Replace it with an unused tip and process the attachment per the previous steps. Any voids detected between the denture and the attachment can be filled outside the mouth or away from the model. The material may be cured using a UV light for 30 seconds or may be allowed to self-cure based on the times described in the table above.

Note: If usable material remains in the syringe, always leave the used tip attached to the syringe.

Storage

Do not store CHAIRSIDE® Attachment Processing Material above 25° C / 77 F°. Only use at room temperature (refrigerated material is more viscous and cures more slowly).

Do not use after expiration date.

Material Handling

Information for proper handling of the material may be found on the l Safety Data Sheet (SDS). This information can be found on the Zest Dental Solutions website (www.zestdent.com).

Disposal

Dispose of used devices which pose a risk of infection according to facility clinical waste procedures and applicable local and state regulations. To dispose of unused material, replace cap and dispose of in accordance with local and state regulations (refer to SDS as appropriate).

NOTICE TO USERS IN THE EUROPEAN UNION

Any serious incident that has occurred in relation to the device(s) in which this Instructions for Use applies should be reported to the manufacturer identified in this Instructions For Use and the competent authority of the Member State in which the user and/or patient is established.

DEFINITIONS OF SYMBOLS

The following symbols may appear on the product packaging or labeling.

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	Manufacturer	Indicates the medical device manufacturer	EN ISO 15223-1	5.1.1
	Authorized Representative in the European Community/European Union	Indicates the authorized representative in the European Community/European Union	EN ISO 15223-1	5.1.2
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	EN ISO 15223-1	5.1.6
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	EN ISO 15223-1	5.1.5
	Consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1	5.4.3
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	EN ISO 15223-1	5.4.2
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process	EN ISO 15223-1	5.2.7
	European Mark of Conformity	Indicates device is in conformance with Medical Device Regulation EU 2017/745EU 2017/745	MDR EU 2017/745	Annex V
Rx only	Rx only	Caution: Federal law restricts this device to sale by or on the order of a dentist	US Code of Federal Regulations, Title 21	801.15(c)(1)(i)(F)
	Medical device	Indicates the item is a medical device	ISO 15223-1	5.7.7
	Unique Device Identifier	Indicates the Unique Device Identifier information	ISO 15223-1	5.7.10
	Quantity	Indicates the number of items within the package	N/A	N/A

	Upper Limit of Temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed	EN ISO 15223-1	5.3.6
	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1	5.1.4

EC REP

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