

IFU SPECIFICATION

Specification # L8116-ZD
IFU Rev A
Document Rev 1
CO # 18-0411

INSTRUCTION FOR USE: CHAIRSIDE IMPRESSION MATERIAL

Approved Supplier: Prestige Printing

Secondary Supplier: Robinson Printing

Specification Requirements:

Printed IFU

1. Print in color
2. Flat Size: 11.0"W x 8.5"H
3. Folded size: 2.75"W x 4.25"H
4. Language: English

Electronic IFU

1. The IFU shall be controlled on the electronic IFU website per QAP-078.

Printed IFU Inspection:

1. Physical IFU must match drawing copy (attached)
2. Verify that the supplier is an approved supplier
3. Inspect per IS-020
4. Verify that the Zest Dental Solutions part number and container quantity are affixed to each package, carton, container or bag

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INSTRUCTIONS

CHAIRSIDE® Impression Material is offered in a variety of formulations. Each formulation is the result of extensive research to provide dependable results, ease of use, and improved clinical performance.

CHAIRSIDE Impression Materials are odorless, tasteless and immersible in disinfectants. They offers dimensional stability, tear resistance, and accuracy of impression.

| CHAIRSIDE | Color | Working Time At 72°F | Setting Time At 72°F |
|-------------------------|------------|----------------------|----------------------|
| Light Body | Yellow | 1 Minute | 2 1/2 Minutes |
| Medium Body (Monophase) | Blue | 1 Minute | 2 1/2 Minutes |
| Heavy Body | Lime Green | 1 Minute | 2 1/2 Minutes |
| Bite Registration | Light Blue | 20 Seconds | 50 Seconds |

MIXING INSTRUCTIONS - CARTRIDGE

1. Insert cartridge into gun, remove twist-off cap, and extrude a 1/4 inch of material, while checking for even flow. Discard the dispensed material and wipe end of cartridge clean.
2. Attach an auto mix tip and squeeze the cartridge handle with smooth, even pressure.
3. Do not remove the automix tip after use. The disinfected used tip serves as a convenient seal until next use.

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SEPARATE FULL ARCH DUAL VISCOSITY IMPRESSION

(Use Light Body and Heavy Body)

1. Apply a thin layer of tray adhesive and allow it to dry at least 5 minutes.
2. Automix. Using a cartridge of Heavy Body and a cartridge of Light Body, bleed a small amount of material from each syringe and discard. Attach a mixing tip to each cartridge and mix simultaneously. Fill the tray with the Heavy Body material and either front-load an intraoral syringe with the Light Body material or attach the intraoral tip and inject directly around the clean, dry preparations. The working time is 1 minute.
3. Slowly but firmly seat the tray in the mouth.
4. After 2 1/2 minutes from the start of the mix, remove the tray from the mouth.

MONOPHASE IMPRESSION (Use Medium Body/Monophase)

Single material impressions can be used where Light Body is not required for high flow. Monophase has a rapid set and fine texture, and is an ideal material to use for simple closed bite impressions as well as a preliminary for temporary crown and bridge material.

1. Syringe Monophase around clean, dry teeth. Syringe into sideless tray.
2. Have the patient close until polymerized. Remove, wash and dry.

CLOSED BITE IMPRESSIONS (Use Light Body and Heavy Body or Light Body and Medium Body/Monophase)

1. Select an appropriate tray. (**Technique Tip:** *It is best to avoid metal trays "bite trays" if a second pour is made in the laboratory. Metal trays tend to distort when the lab pries the first cast out of the impression, precluding an accurate second pour.*)
2. The impression should be taken using two viscosities simultaneously: Heavy Body or Medium Body/Monophase in the tray for dimensional stability and a wash of Light Body for detail. The key to this procedure is to syringe Light Body onto clean, dry teeth, then blow thin air until only a thin film remains. If a blank area remains, dry, syringe, and blow again, until only the thin film remains. Add Light Body to cover tooth, then seat tray.
3. Have patient close onto a tray of Heavy Body or Medium Body/Monophase and guide patient into a centric occlusion closure. It is important to rehearse the proper closure beforehand.
4. Water wash and dry the impression after removal from the mouth.

BITE REGISTRATION

CHAIRSIDE Bite Registration Material is dimensionally very stable. Use where flexibility is not required.

ADDITIONAL NOTES:

- ☐ CHAIRSIDE Impression Materials should be brought to room temperature prior to use. Exposure to prolonged temperatures above 77°F can be damaging. Store at room temperature.
- ☐ CHAIRSIDE Impression Materials are compatible with all other vinyl polysiloxane materials.
- ☐ Powder from gloves can impair set. Sample test is suggested.
- ☐ High viscosity materials used alone are not suitable for detailed impressions.
- ☐ Light Body impression materials used alone can flex excessively and may result in distortion.