

CHROMA ZONE™ **COLOR STAIN**

CHROMA ZONE™ COLOR STAIN Instruction for Use

KURARAY MEDICAL INC.

CONTENTS

| | |
|--|----|
| ● Introduction | 3 |
| ● Precautions | 4 |
| ● Indications | 5 |
| ● Contraindication | 5 |
| ● Feature | 5 |
| ● System components | 6 |
| ● Related product | 7 |
| ● Instructions for use | 8 |
| 1. Flow chart | 8 |
| 2. Light curing unit, curing time and properties | 8 |
| 3. Laboratory work | 9 |
| 1. Color characterization of composite resin for crown and bridge | 9 |
| 1) Older age teeth | 9 |
| 2) Middle age teeth | 11 |
| 3) Youth teeth | 11 |
| 2. Color characterization of composite resin inlay | 12 |
| ● Troubleshooting | 14 |

Introduction

- Please review the Instructions for Use carefully before using the product.
- After reviewing, keep the manual in a convenient place for quick reference if necessary. If the manual is lost, please contact the distributor.
- This product should be used by dentists or dental technicians.
- This product should be used only for the indications in the manual.

[Caution]: Items may affect the safety.

[Note] 1) Items may cause material problems.

2) Recommendable or detailed procedures.

Precautions

<Safety instructions>

[For the patients]

1. The product should not be used for patients with a history of hypersensitivity to methacrylate monomers.

If any hypersensitivity occurs, such as a rash or dermatitis, consult a physician.

[For the operators]

1. Avoid any direct contact to prevent hypersensitivity.
If the product comes in contact with the skin, immediately wipe it off with a cotton pledget moistened with alcohol and then wash it with copious amounts of water.
If any hypersensitivity, such as a rash or dermatitis, occurs from contact with the product, discontinue the use of the product and consult a physician.
If the product gets in the eye, immediately wash the eye with copious amounts of water and consult a physician.
2. Use safety equipment such as a local vacuum unit, a protective shield, and a dustproof mask approved by an appropriate organization. This is to prevent the operator from inhaling dust when shaping or polishing composite resin.

<Precautions for fabricating>

Keep the indications and procedures specified by the manufacturer.

Do not use the product in conjunction with other companies' color characterizing material.

In particular, use the following cautions to prevent fracture of composite resin for crown and bridge or composite resin inlay:

- 1) Use the light-curing unit and curing time specified in the Instructions.
- 2) Do not mix the product with composite resin, to prevent air entrapment in composite resin or the impaired physical properties.

<Precautions for handling>

1. After application of the product, wash the brushes with ethyl alcohol or self-curing resin monomer solution.
2. Avoid unnecessary exposure to direct sunlight or operatory lights; the material may harden during use.
3. The product when is applied directly to the finished resin surface may come off in a short period of time in the oral cavity. It is recommended, therefore, to sandwich the product between two layers of composite resin using the internal staining method. Staining pits and fissures in the posterior area can be performed directly.

<Precautions when storing the product>



1. Do not use after expiration date. Note expiration date on outside of the package.



2. The product should not be stored in direct sunlight or in a place where high temperature or humidity is anticipated.

Indications

This product is designed to be used for developing color characterization

1. Composite resin for crown and bridge

Facing crown

Jacket crown

2. Composite resin inlay

Contraindication

Staining of denture bases

Feature

A variety of shades available

Eleven shades are available to meet optimal color matching requirements.

The product is applied by using the internal staining method. It also can be mixed with the Clear Paste to reproduce delicate color.

System components

The CHROMA ZONE COLOR STAIN consists of 11 Stain pastes, the Clear Paste, and accessories.

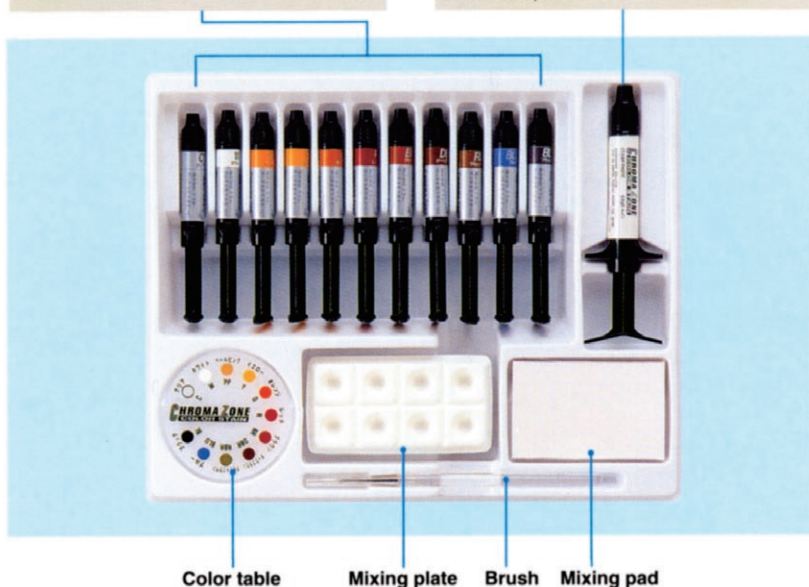
● **Stain pastes (11 shades) (0.5 ml each)**

Clear, white, pale pink, yellow, orange, red, brown, dark brown, russet brown, blue, and black

Light-cured, low-viscosity composite resin pastes that are used for the color characterization of composite resin for crown and bridge or composite resin inlay.

● **Clear Paste (2.0 g / 1.2 ml)**

High-viscosity light-cured composite resin that is used to adjust the viscosity of the stain pastes. The Clear Paste is used with each stain paste.



● All components are available as refills.

Related product

※Read the respective Instructions for Use prior to use.

[Light-cured composite resin for crown and bridge]

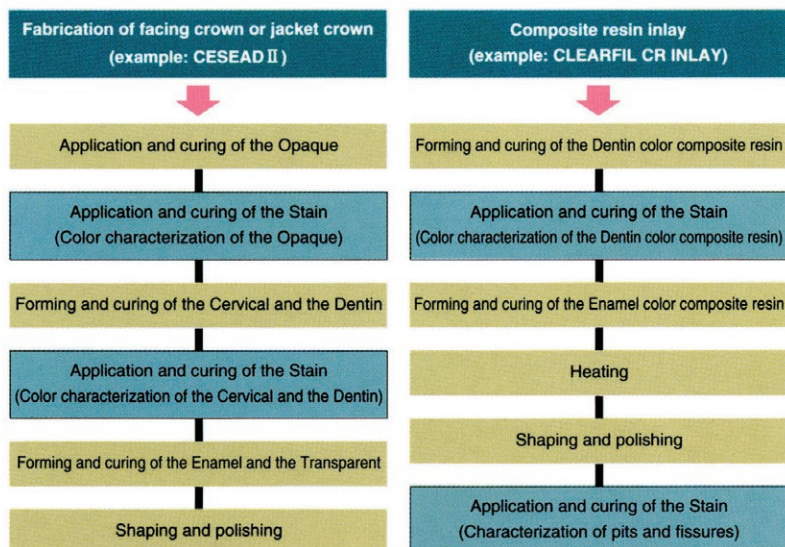
CESEAD II is a light-cured composite resin for crown and bridge consisting of metal-adhesive primer and hybrid composite resin that features excellent mechanical strength, abrasion resistance, and discoloration resistance.

CESEAD II (KURARAY MEDICAL INC.)



Instructions for use

1. Flow chart



※CESEAD II (KURARAY MEDICAL INC.)
CLEARFIL CR INLAY (KURARAY MEDICAL INC.)

2. Light curing unit, curing time and properties

The following laboratory light-curing unit can be used for curing the CHROMA ZONE COLOR STAIN.

1) Curing time

| Light-curing unit | Curing time (sec) |
|-------------------|-------------------|
| Dentacolor-XS | 30 |

2) Curing characteristics

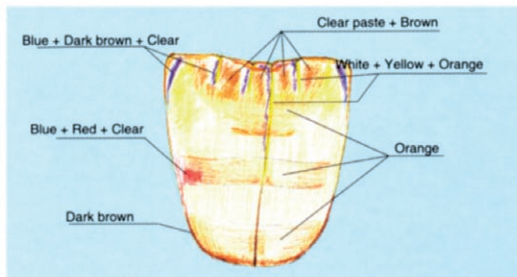
| Color | Depth of cure (mm) |
|-------------|--------------------|
| | Dentacolor-XS |
| Clear | 4.52 |
| White | 1.25 |
| Dark Brown | 0.28 |
| Clear Paste | 1.73 |

※Data were measured by KURARAY MEDICAL INC.
The depth of cure was measured according to ISO 4049.
Dentacolor-XS (Heraeus Kulzer GmbH)

3. Laboratory work

1. Color characterization of composite resin for crown and bridge

1) Older age teeth



Example of color characterization for older age teeth

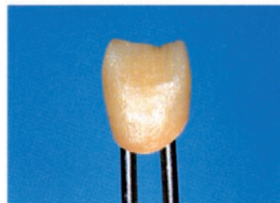
1. Applying and curing the Opaque

Apply the Body Opaque paste. If color correction is necessary, apply the Opaque Modifier.



2. Forming and curing the Cervical paste and the Dentin

Form the Cervical paste and the Dentin paste, and then cure the pastes preliminarily.



3. Preparing the Stain

Be sure to have the required amount of paste.

[Caution] Be careful to avoid the paste contacting exposed skin.

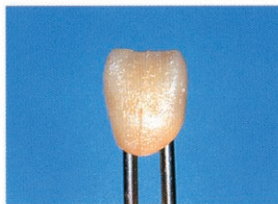


4. Applying and curing the Stain

Apply the stain pastes to develop the desired color.

[Caution] To prevent impairment of the material's physical properties from air entrapment, do not mix the Stain paste with the composite resin.

[Note] Do not expose the Stain pastes to direct sunlight or operator lights ; the material may harden during application.

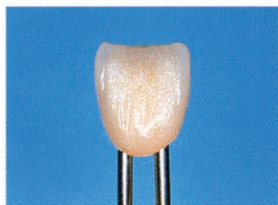


5. Reproducing the incisal edge color

(Mixing with the Clear Paste and forming the mixture)

To reproduce the transparency of the incisal edge, form the area using a mixture of Stain and Clear Paste, then cure this area with the light-curing unit for the specified time.

The next step is to apply the Amber paste thinly on the incisal edge and the Transparent paste in the adjacent areas, followed with final light polymerization.



| Light-curing unit | Curing time (sec) |
|-------------------|-------------------|
| Dentacolor-XS | 30 |

[Caution] Use the specified light curing unit and observe the specified curing time.

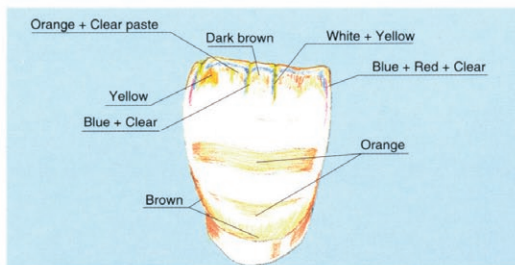
6. Completion

Shape and polish the work in the usual manner.

[Caution] Use safety equipment such a local vacuum unit and a dustproof mask approved by an appropriate organization.



2) Middle age teeth



Example of color characterization of middle age tooth

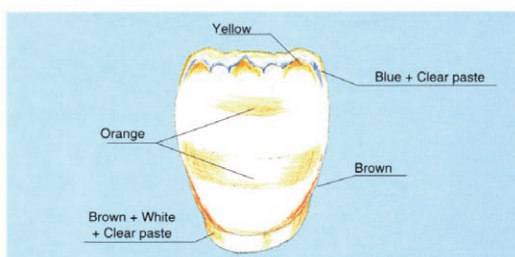


Applying and curing the Stain paste

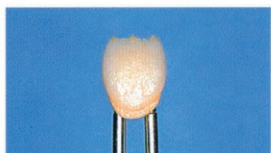


Completed work

3) Youth teeth



Example of color characterization of youth tooth

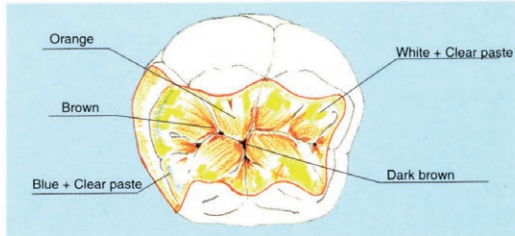


Applying and curing the Stain paste



Completed work

2. Color characterization of composite resin inlay



Example of color characterization of composite resin inlay

1. Forming and curing the Dentin composite resin.

Form the Dentin composite resin paste and cure.



2. Preparing the Stain pastes

Be sure to have the required amount of paste.

Be sure to avoid the pastes contacting exposed skin.

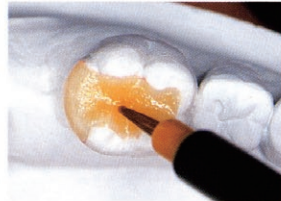


3. Color characterization of the Dentin color composite resin

Characterize the occlusal surface or cervical area.

[Caution] To prevent impairment of the material's physical properties from air entrapment, do not mix the Stain pastes with the composite resin.

[Note] Do not expose the Stain pastes to direct sunlight or operatory lights; the material may harden during application.



4. Curing the Stain pastes

After application, cure the Stain pastes with the light-curing unit for the specified time.

| Light-curing unit | Curing time (sec) |
|-------------------|-------------------|
| Dentacolor-XS | 30 |

[Caution] Use the specified light curing unit for the specified curing time.



5. Forming and curing the Enamel color composite resin

Form the Enamel composite resin on the cured stain.



6. Shaping and polishing

Shape and polish the work in the usual manner.

[Caution] Use safety equipment such as a local vacuum unit and a dustproof mask approved by an appropriate organization.



7. Characterizing pits and fissures

Characterize the pits and fissures and cure the pastes with the following light-curing unit for the specified curing time.

| Light-curing unit | Curing time (sec) |
|-------------------|-------------------|
| Dentacolor-XS | 30 |

[Caution] Use the specified light curing unit for the specified curing time.



8. Completion



Troubleshooting

Below are some potential troubles that might be encountered in using CHROMA ZONE COLOR STAIN and their possible causes and remedies. For further information, please contact your distributor.

| Trouble | Possible cause | Remedy |
|---|--|---|
| ● Poor curing of the Stain pastes | Poor intensity of curing light | Check bulb on burning out or service life. |
| | Improper exposure position | Make sure to place light curing unit in specified operating position. In particular, the inner side of bridges or pontics should be exposed to light several times with changing positions. |
| | Specified light curing unit is not used. | Use the specified light curing unit. See 2. Curing time and properties on page 8. |
| ● The Stain pastes hardened during use. | Exposure to strong light | Do not use the Stain pastes under direct sunlight or operatory lights. |
| ● Hardened Stain pastes or Clear Paste | Improper storing | The product should not be stored in the direct sunlight or in a place where high temperature or humidity is anticipated. Also do not use after expiration date. After the resin is dispensed, the applicator cap should be replaced as soon as possible and stored in an appropriate place. |

WARRANTY

All data is based on actual measurements performed by KURARAY MEDICAL INC.

All information contained herein is presented in good faith and without warranty.

KURARAY MEDICAL INC will replace any product that is proved to be defective.

KURARAY MEDICAL INC does not accept liability for any loss or damage, direct, consequential or special, arising out of the application or use of or the inability to use these products.

Before using, the user shall determine the suitability of the products for the intended use and the user assumes all risk and liability whatsoever in connection therewith.

NOTE

CHROMA ZONE, CESEAD and CLEARFIL are trademarks of Kuraray Co., Ltd.

Dentacolor is a trademark of Heraeus Kulzer GmbH.

Manufactured by

KURARAY MEDICAL INC.

1621 Sakazu, Kurashiki, Okayama 710-8622, Japan