Directions for Use

Universal Nano-Ceramic™ Restorative
Ceram-X™ is a light cured, radiopaque restorative material for restoration of anterior and posterior teeth. Ceram-X combines Nanotechnology, proprietary to DENTSPLY and known from Prime&Bond® NT, with improved organically modified Ceramic particles, resulting in a Nano-Ceramic Restorative with unique features. Thus, Ceram-X offers natural aesthetics by simple procedure, extraordinary low monomer release and superior handling characteristics.

Ceram-X provides the convenient Natural-Shade™ system: two shading systems in one product cover all clinical and aesthetic demands for anterior and posterior teeth.

Ceram-X mono, the Single Translucency System, comprises seven shades of intermediate translucency comparable to conventional composites (e.g. Spectrum® TPH®), optimal for fast and easy restorations of posterior or anterior teeth.

Ceram-X duo, the Double Translucency System, offers four dentin shades with translucencies of natural dentin and three enamel shades which mimic natural enamel. Their design has been optimized for highly aesthetic restorations with a minimum number of shades. For the enamel shades, the unique Nano-Ceramic matrix in combination with the optimized filler particle size distribution create an ideal balance between handling and optical characteristics. Additionally, Ceram-X duo comprises one bleach dentine shade for the restoration of bleached teeth.

The Ceram-X i-shade label eases shade selection, covering the whole Vita® classical shade range for both the Ceram-X mono and duo system.

Ceram-X is to be used with either total-etch nano-technology dental adhesive Prime&Bond NT or the single-step self-etching adhesive Xeno® III.

1 Vita is a registered trademark of Vita Zahnfabrik H. Rauter GmbH & Co. KG, Bad Säckingen, Germany.
The **Ceram·X** restorative system is available in predosed Compules® Tips and Easy-Twist™ syringes.

**Caution:** For dental use only.

**COMPOSITION**

Methacrylate modified polysiloxane
Dimethacrylate resin
Fluorescence pigment
UV stabilizer
Stabilizer
Camphorquinone
Ethyl-(dimethylamino)benzoate
Barium-aluminium-borosilicate glass
Methacrylate functionalised silicon dioxide nano filler
Iron oxide pigments and titanium oxide pigments and aluminium sulfo silicate pigments according to shade

**INDICATIONS FOR USE**

Direct restorations of all cavity classes in anterior and posterior teeth.

**CONTRAINDICATIONS**

Known allergy to methacrylate resins or any other of the components.

**WARNINGS**

- **Ceram·X** contains methacrylates which may be irritating to skin and eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of soap and water. Do not take internally.
- **Ceram·X** contains polymerizable monomers which may cause skin sensitization (allergic contact dermatitis) in susceptible persons. Wash thoroughly with soap and water after contact. If skin sensitization occurs, or if a known allergy to methacrylate resin exists, discontinue use.

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2 Organically modified ceramic.
PRECAUTIONS
When using Ceram·X Compules tips, use a gentle, even motion when exerting pressure on the applicator gun. Use of excessive force or sudden movement could create a potential hazard with extrusion.

ADVERSE REACTIONS
The following adverse reaction has been associated with the use of polymerisable monomers:
• Skin sensitization (allergic contact dermatitis).

INTERACTIONS WITH OTHER DENTAL MATERIALS
Eugenol and hydrogen peroxide containing dental materials should not be used in conjunction with these products because they may prevent setting and cause softening of the polymeric components of the material.

STEP-BY-STEP INSTRUCTIONS
Shade Selection
The Ceram·X Nano-Ceramic Restorative comprises two separate shading systems:
• Ceram·X mono, the Single Translucency System with seven shades for clinical standard situations (Mono M1, M2, M3, M4, M5, M6 and M7) and
• Ceram·X duo, the Double Translucency System with four dentin shades (Duo D1, D2, D3 and D4) and three enamel shades (Duo E1, E2 and E3) for aesthetically demanding cases. Within Ceram·X duo, one bleach dentin shade (Duo DB) is available for the restoration of bleached teeth.
A) Shade selection using the Vitapan®<sup>3</sup> classical shade guide

The Ceram·X shades are comparable to the Vitapan classical shade guide. Thus, it is possible to select the tooth color to be restored from a Vitapan classical shade guide for both the Ceram·X mono and the Ceram·X duo system:

**Ceram·X mono** (Single Translucency System)

Refer to the central regions of the natural tooth and the Vita shade fingers. Chose the Vita shade most closely matching the tooth color.

Seven Ceram·X mono shades of intermediate translucency are available for restorations in Single Translucency Technique. Each Ceram·X mono shade is suitable for several similar Vita shades. Having determined the tooth color by means of a Vitapan classical shade guide, select the corresponding Ceram·X mono shade from the below table:

**Ceram·X duo** (Double Translucency System)

Consider the color of the natural tooth and the Vita shade fingers in their whole extent. Chose the Vita shade most closely matching the tooth color.

Four Ceram·X duo dentin shades with translucencies of natural dentin and three enamel shades with translucencies of natural enamel are available. In combination, the available Ceram·X duo dentin and enamel shades cover the whole Vitapan classical shade range. Having determined the tooth color by means of a Vitapan classical shade guide, select the corresponding combination of Ceram·X duo dentin and enamel shades from the below table:

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<sup>3</sup> Vitapan is a registered trademark of Vita Zahnfabrik H. Rauter GmbH & Co. KG, Bad Säckingen, Germany.
Note: depending on the thicknesses of the respective layers, the optical result may vary from the considered Vita shade!

For a quick survey over the Vita corresponding Ceram-X mono and duo shades, the delivered Shade Identification Label (i-shade label) can be used. It is recommended to fix the label on the rear side of the Vita shade guide holder.

<table>
<thead>
<tr>
<th>Ceram-X</th>
<th>Duo</th>
<th>Enamel</th>
<th>D1</th>
<th>D2</th>
<th>D3</th>
<th>D3</th>
<th>D4</th>
<th>D4</th>
<th>D3</th>
<th>D3</th>
<th>D3</th>
<th>D3</th>
<th>D3</th>
<th>D3</th>
<th>D3</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>A2</td>
<td>A3</td>
<td>A3.5</td>
<td>A4</td>
<td>B1</td>
<td>B2</td>
<td>B3</td>
<td>B4</td>
<td>C1</td>
<td>C2</td>
<td>C3</td>
<td>C4</td>
<td>D2</td>
<td>D3</td>
<td>D4</td>
</tr>
</tbody>
</table>

B) Shade selection with delivered Ceram-X shade fingers
Alternatively, the Ceram-X shade fingers delivered can be used for shade selection. For both the Ceram-X mono and the Ceram-X duo system, shade fingers made from original material are provided in two separate shade guide holders.

Ceram-X mono (Single Translucency System)
Refer to the central region of the natural tooth. Chose the Ceram-X mono shade most closely matching the tooth color.

Ceram-X duo (Double Translucency System)
For selection of a suitable Ceram-X duo dentin shade, consider the cervical region of the natural tooth or the color of the moist dentin as visible in the cavity. It is recommended to apply a darker rather than a lighter dentin shade, since the succeeding enamel layer will tend to lighten the resulting optical effect. For selection of the suitable Ceram-X duo enamel shade,
consider the incisal, occlusal or proximal region of the natural tooth. Choose the dentin shade and the enamel shade most closely matching the tooth colors compared to, respectively.

Shades should be selected while the teeth are hydrated. Clean the tooth with a prophylaxis paste (e.g. Nupro®) to remove any extraneous plaque or surface stain. Be aware of room and ambient light effects on shade selection (ideal light is northern exposure with natural daylight). Observe tooth shades for short periods of time to neutralize the effect of extended shade viewing comparisons. Viewing a grey-blue background will have a relaxing effect on the viewing operator’s photo/color optic discrimination. Eyes should be rested. It might be useful to have ancillary corroboration on shade selection by dental personnel.

Cavity Preparation
Cavity design requirements are essentially a conventional preparation with refinement of cavo-surface margins for enhancement of acid-etching.

No residual amalgam or other base material should be left on the internal surfaces of the preparation which would interfere with light transmission and the hardening of the restorative.

Clean uninstrumented enamel and dentin with a rubber cup and pumice or a non-fluoride cleaning paste such as Nupro prophylaxis paste. Wash thoroughly with water spray and air dry. Clean freshly instrumented enamel and dentin with water spray and then air dry.

Do not desiccate!

Moisture Control
Surface cleanliness is paramount for the development of adhesion. Isolate prepared tooth from contamination with saliva, sulcus fluid, or blood with adequate measures (e.g. cotton rolls or dental dam).
Pulp Protection and Base
In deep cavities cover the dentin close to the pulp (less than 1 mm) with a hard-setting calcium hydroxide liner (Dycal®) leaving the rest of the cavity surface free for bonding with Prime&Bond NT or Xeno III.

Placement of the Matrix
Use a matrix system (e.g. Automatrix® or Palodent®) with proper wedging for proximal contacts. Pre-wedging is advocated to achieve slight separation and facilitate optimal proximal contact. In class II cavities the use of a deadsoft, thin matrix band and subsequent burnishing of the matrix band will improve final interproximal contact and contour.

Conditioning and application of adhesive
Prior to the application of Ceram-X the cavity has to be conditioned and/ or treated with a dental adhesive. For application please follow the directions for use of the respective product. It is recommended to use Ceram-X in combination with the total-etch nano-technology dental adhesive Prime&Bond NT or with the single-step self-etch adhesive Xeno III. In cases where the application of a HEMA containing adhesive is not desired, the use of Prime&Bond NT is recommended.

Application of Ceram-X Universal Nano-Ceramic Restorative
Using Compules tips
Insert Compules tip of chosen shade into the applicator gun barrel. Be certain that the collar on the Compules tip is inserted first. Remove the cap from the Compules tip. The Compules tip may be rotated to gain the proper angle of entrance into the cavity. To dispense the material, use a slow, steady pressure. Excessive force is not necessary. Dispense Ceram-X directly into the cavity.
Using Easy-Twist syringes
Dispense the necessary amount of Ceram-X restorative material from the Syringe onto a mixing pad by turning the handle slowly in a clockwise direction. To prevent oozing of the material when dispensing is completed, point the front tip of the syringe upwards and turn the handle counter-clockwise. Immediately re-close the syringe with the respective cap. Place Ceram-X in increments into the cavity and protect remaining material against light.

Rebuilding the tooth following either Single or Double Translucency Technique
Prior to the application of Ceram-X mono or duo shades, a flowable restorative material (e.g. X-flow™) can be used for e.g. cavity lining. For application please follow the directions for use of X-flow.

Ceram-X mono (Single Translucency System)
Fill the complete defect with the chosen Ceram-X mono shade (with reference to incremental polymerisation technique).

Ceram-X duo (Double Translucency System)
Rebuild the tooth with respect to the anatomical conditions. First rebuild a dentin core with the suitable Ceram-X duo dentin shade. In a second step, add an enamel layer with the suitable Ceram-X duo enamel shade. It is advisable to apply Ceram-X duo enamels in a comparably thin layer, not exceeding the thickness of natural enamel. In the anterior area a silicon matrix (prefabricated under assistance of a mock-up) can facilitate the establishment of the anatomical form.
In any case incremental placement (in 2 mm layers or less) is recommended to minimize polymerization shrinkage. Light cure each increment according to the below table:

<table>
<thead>
<tr>
<th>Shade Description</th>
<th>Time 1</th>
<th>Time 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceram-X mono shades (M1 to M7)</td>
<td>20 sec</td>
<td>20 sec</td>
</tr>
<tr>
<td>Ceram-X duo dentin shades (D1 to D4 and DB)</td>
<td>40 sec</td>
<td>30 sec</td>
</tr>
<tr>
<td>Ceram-X duo enamel shades (E1 to E3)</td>
<td>10 sec</td>
<td>10 sec</td>
</tr>
</tbody>
</table>

When using a LED curing device, curing time according to manufacture’s instructions should be applied. When using a LED curing device, curing time according to manufacture’s instructions should be applied. When using a LED curing device, curing time according to manufacture’s instructions should be applied. When using a LED curing device, curing time according to manufacture’s instructions should be applied.

When using the SmartLite™ PS High-Power LED curing light, curing times for Ceram-X shades mono M1, M2 and M3 are reduced to 10 seconds.

Check curing light for minimum curing output of at least 500 mW/cm².

Finishing and Polishing

Begin finishing immediately after final curing. For removal of excess and contouring finishing burs or diamonds may be used.

Additional finishing and polishing is obtained by using Enhance™ Finishing Discs, Cups or Points. Alternatively, other standard aluminium oxide disc series may be used. Prior to proceeding to the use of polishing Discs, Cups or Points restoration surface should be finished to a final outline form and desired contour and anatomical features. Surface should be smooth and defect free.

For achieving a very high luster of the restoration use PoGo® Polishers or Prisma®-Gloss™ regular paste followed by Prisma-Gloss Extrafine polishing paste with Enhance polishing foam cups.
MAINTENANCE OF THE COMPULES TIP APPLICATOR GUN
The applicator gun is sterilizable by autoclave (2.1-2.4 bar/135-138 °C). Alternatively, suitable disinfecting solutions can be applied following the manufacturers’ instructions. Do not continue use of damaged and/or soiled applicator gun.
It is recommended that the applicator gun be disassembled for assured sterilization. Partially close the applicator gun and place thumb under the rear portion of the hinge. Push upward and lift hinge separating the applicator gun, exposing the plunger. Remove residual composite with a soft paper tissue and a suitable solvent (70 % alcohol).
To reassemble, insert plunger into applicator gun barrel, press components together and snap hinge mechanism in place.

STORAGE
Store at room temperatures between 6 and 28 °C. Inadequate storage conditions will shorten the shelf life and may lead to malfunction of the product.

Unsealed Compules tips or syringes
In order to benefit from optimal handling properties, storage of unsealed Compules tips or syringes in a dry environment (< 80 % relative humidity) protected from sunlight and used within 3 months is recommended.
All products should be used at room temperature.

BATCH NUMBER AND EXPIRY DATE
The batch number should be quoted in all correspondence, which requires identification of the product.
Do not use after expiry date.
If you have any questions, please contact:

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