

ENGLISH

CAUTION
FOR PROFESSIONAL DENTAL USE IN RECOMMENDED INDICATIONS ONLY (SEE 2. INDICATIONS FOR USE).

1. Product description

Ceramir® Bioceramic Implant Cement is a permanent, radiopaque dental adhesive cement. It is self-setting and the powder is calcium aluminate and in the liquid water. The setting reaction occurs as a result of a chemical reaction, it is self-setting.

In Ceramir Bioceramic Implant Cement QuikCap, the cement is supplied in a capsule and is used in a direct application. The minimum volume of mixed cement delivered from one capsule is 0.17 ml.

A capsule applicator and a mixing device are required for use. We recommend Cerami Applicator and Cerami Applicator 2 from Doxa Dental AB.

2. Indications for use

Ceramir Bioceramic Implant Cement is intended for permanent cementation on anatomical abutments of:

- Metal and porcelain fused to metal restoration
- High-strength ceramometal restorations suitable for conventional cementation (e.g. zirconia, alumina, and lithium disilicate)

Precautions

Ceramir Bioceramic Implant Cement contains polyacrylic acid, which may be irritating to eyes and skin. Avoid contact with eyes. In case of skin contact, rinse with plenty of water. In case of contact with eyes, rinse immediately with water and seek medical advice.

Do not use on patients with known allergy to polyacrylic acid. In rare cases, the product may cause sensitivity to some persons. If such reactions are observed, discontinue the use of the product and consult a physician.

3. Step-by-step instructions

Note: Do not use pre-treatment agents, e.g. slimes, primers or bonding agents when cementing with Ceramir Bioceramic Implant Cement. Use of such pre-treatments may compromise the bonding of the cement.

3.1 Abutment preparation

Remove temporary cement and rinse with water.

Air dry gently with dry air.

Dry the operation field with for example cotton rolls.

3.2 Preparation of the restoration

Lithium Disilicate

Etch with HF acid according to manufacturer's instructions. Do not use any pre-treatment agents, e.g. slimes, primers or bonding agents.

All other restorations

Do not use any pre-treatment agents, e.g. slimes, primers or bonding agents when cementing with Ceramir Bioceramic Implant Cement. Use of such pre-treatments will destroy the bond between cement and restoration.

Air abrasion can be used if recommended by the restoration manufacturer.

3.3 Activation

ATTENTION: WORK QUICKLY

Start mixing immediately following activation (the reaction between the liquid and powder starts directly after activation).

- Open the aluminum pouch and remove the capsule.

- Hold the capsule firmly against a hard, flat surface with the plunger facing down (fig. 1).

- Push down firmly, forcing the plunger into the body of the capsule until it stops (fig. 1).

3.4 Mixing

- Immediately mix the capsule into the applicator using the groove to hold the capsule (fig. 2).

- Gently close the dosage lever (fig. 3a) two times to push the cement towards the plunger.

- Then apply the cement by gently squeezing the lever two more times (fig. 3b).

- After application, remove the empty capsule using the applicator release button (fig. 4).

Working and setting times

• Working time from end of mixing at 23°C/73°F: 2 minutes.

• Setting time from start of mixing at 23°C/73°F: 2 minutes.

Note: Room temperatures above 23°C/73°F will accelerate setting and reduce the working time available.

3.6 Sealing and finishing

• Seal the restoration and stabilize it under pressure, to avoid any movements, until the cement reaches a rubber-like consistency (approx. 10 min).

• Remove excess material when the cement has reached the rubber-like consistency (fig. 8).

• Keep the restoration stable for an additional 4 minutes (fig. 9).

• Clean the excess around the margins of the restoration (especially the gingival sulcus) and remove any remaining cement.

• Advise the patient not to load their restoration for the first hour after cementation.

4. Cleaning the applicator

Cerami Applicator can be cleaned with standard cleaning agents, e.g. alcohol-based disinfectants.

Cerami Applicator 2 with alcohol coded gaze.

IMPORTANT: Regularly apply dental instrument lubricant. Do not use chemical sterilants/disinfectants as these may cause damage to the applicator.

AUTOCLOAVING: Autoclave up to a maximum temperature of 140°C. Follow autoclave manufacturer's instructions for use. Do not ultrasonic clean.

5. Storage and shelf life

Keep Ceramir® Bioceramic Implant Cement QuikCap capsules at temperatures between 4°C/39°F and 25°C/77°F. Do not open the aluminum pouch until immediately before use.

Do not use Ceramir Bioceramic Implant Cement QuikCap capsules after their expiry date.

Warning
Doxa Dental AB warrants that the Product will be free from defects in material and manufacture. This warranty shall (i) only apply within the Product's shelf life/expiry date (the "Warranty Period") and (ii) further only if the defect is due to a manufacturing or design defect in the Product. EXCEPT WHERE PROHIBITED BY LAW, DOXA DENTAL AB WILL NOT BE LIABLE FOR ANY LOSS OR DAMAGE ARISING FROM THE USE OF THIS PRODUCT, WHETHER DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL INCLUDING LOSS OF PROFITS, REGARDLESS OF WHETHER ASSESSMENT, INCLUDING WARRANTY, BREACH OF CONTRACT, OR NON-INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS. Users are responsible for determining the suitability of the Product for their application.

Limitation of liability

This Product is found defective within the Warranty Period, your exclusive remedy will be to return the Product to Doxa Dental AB for repair or replacement or the Doxa Dental AB Product. EXCEPT WHERE PROHIBITED BY LAW, DOXA DENTAL AB WILL NOT BE LIABLE FOR ANY LOSS OR DAMAGE ARISING FROM THE USE OF THIS PRODUCT, WHETHER DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL INCLUDING LOSS OF PROFITS, REGARDLESS OF WHETHER ASSESSMENT, INCLUDING WARRANTY, BREACH OF CONTRACT, OR NON-INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS. Users are responsible for determining the suitability of the Product for their application.

Trademarks

Ceramir® is a trademark of Doxa Dental AB.

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The extended symbols glossary is provided electronically at <http://ceramir.us.com/symbols/>

Batch code
 Temperature limitation
 Use by
 Catalogue number
 Consult instructions for use
 Manufacturer
 Caution

FRANÇAIS

1. Description du produit

Ceramir® Bioceramic Implant Cement est un ciment permanent, radiopaque destiné à la fixation permanente d'implants dentaires. Il est composé de calcium aluminate et de l'eau liquide. Ce ciment dentaire, qui se durcit par réaction chimique possède des caractéristiques d'autofixation.

Dans Ceramir Bioceramic Implant Cement QuikCap, le ciment est livré dans une capsule pour la mise en application directe. Le volume minimal de ciment mesuré que se obtiene avec une capsule est de 0.17 ml.

Un applicateur et un appareil de malaxage sont requis pour son utilisation.

Nous recommandons Cerami Applicator et Cerami Applicator 2 de Doxa Dental AB.

2. Indications d'emploi

Ceramir Bioceramic Implant Cement est indiqué pour le scellement permanent sur éponges d'implants.

- De restorations en métal et émail fusionné pour les restaurations en métal.

- Restaurations céramiques résistantes adaptées pour la fixation conventionnelle (par exemple, dióxido de zirconio, oxyde d'aluminio et oxyde d'yttrium).

Précautions d'emploi

Ceramir Bioceramic Implant Cement contient de l'acide polyacrylique, qui peut être irritant pour les yeux et la peau. Avoider tout contact avec les yeux. En cas de contact avec les yeux, rincer immédiatement avec de l'eau claire. En cas de contact avec la peau, éviter l'abandonnement à l'eau claire. En cas de contact avec les yeux, rincer immédiatement avec de l'eau claire.

Ne pas utiliser sur les patients ayant des allergies connues à l'acide polyacrylique. Dans de rares cas, ce produit peut provoquer une sensibilité chez certaines personnes. Si une telle réaction survient, arrêter l'utilisation du produit et consulter un médecin.

3. Instructions à suivre pas-à-pas

Notes: Ne utilisez pas de pré-traitement agents, par exemple, silanes, primers ou agents de liaison avec Ceramir Bioceramic Implant Cement. L'utilisation d'un pré-traitement de ce type peut compromettre l'adhésion du ciment.

3.1 Abutment preparation

• Retirez temporairement le ciment et rincez avec de l'eau.

• Secouez le gicleur de levier (fig. 3a) deux fois pour le nettoyer vers l'arrière.

• Secouez le chapeau opérateur, par exemple à l'aide de rouleaux de coton hydrophile.

3.2 Préparation de la restauration

Disolcado de litio

Mondez avec l'acide HF selon les instructions du fabricant. Ne utilisez pas de produits de pré-traitement ou lants.

Toutes les autres restaurations

• Ne utilisez pas de pré-traitement agents, par exemple, silanes, primers ou agents de liaison avec Ceramir Bioceramic Implant Cement. L'utilisation d'un pré-traitement de ce type peut compromettre l'adhésion du ciment.

3.3 Activación

ATENCIÓN: ¡TRABAJA RÁPIDAMENTE!

Comenzar a mezclar inmediatamente después de la activación (la reacción entre el agua y el polvo comienza directamente después de la activación).

- Abrir la bolsa de aluminio y sacar la cápsula.

- Sujetar la cápsula firmemente y aplicar agua.

- Secar la zona de la intervención usando, por ejemplo, rollos de algodón hidrófilo.

3.4 Mixaje

- Colocar inmediatamente la cápsula en un dispositivo de malaxado o en una mezcladora de rotación (4.000 a 5.000 rpm) o en una mezcladora rotativa.

- Mezclar inmediatamente la cápsula con el aplicador utilizando las ranuras para mantenerla en su sitio (fig. 4).

3.5 Aplicación

- Colocar inmediatamente la cápsula en el aplicador utilizando las ranuras para mantenerla en su sitio (fig. 4).

- Efectuar dos presiones ligeras sobre el levere de dosificación (fig. 3a) para limpiar el aplicador.

- Aplicar suavemente el aplicador en la boca del paciente apoyando con ambas manos el levere de dosificación (fig. 3b).

- Para aplicación, retira la cápsula vidrio de la boca del paciente.

3.6 Preparación de la restauración

Disolcado de litio

Mondez con ácido fluorídico (HF) de acuerdo con las instrucciones del fabricante. No utilice productos de pre-tratamiento o lants.

Todos las demás piezas de restauración

• No utilice productos de pre-tratamiento, como por ejemplo, silanes, primers o agentes de liaison avec Ceramir Bioceramic Implant Cement. L'utilisation d'un pré-traitement de ce type peut compromettre l'adhésion du ciment.

3.7 Almacenamiento y período de validez

• Mantenga las cápsulas de Ceramir Bioceramic Implant Cement QuikCap a una temperatura comprendida entre 4°C y 20°C. Abra la bolsa de aluminio rápidamente tras su uso.

• No utilice cápsulas de Ceramir Bioceramic Implant Cement QuikCap después de la fecha de caducidad.

3.8 Marcas registradas

Ceramir® es una marca registrada de Doxa Dental AB.

Última revisión: 2019-01-16

Radio-opaque
 Capsule
 Applicator

AVERTISSEMENT

Ne pas utiliser aucun agent de pré-traitement (silane, primaire ou lant) lorsque cimentant avec Ceramir Bioceramic Implant Cement. L'utilisation d'un pré-traitement de ce type peut compromettre l'adhésion du ciment.

5. Stockage et conservation

Conserve Ceramir® Bioceramic Implant Cement QuikCap capsules à une température comprise entre 4°C et 20°C. Ne pas ouvrir l'opercule sans avoir été recommandé par le fabricant.

Ne pas utiliser les capsules Ceramir Bioceramic Implant Cement QuikCap après la date d'expiration.

Marques commerciales

Ceramir® es una marca registrada de Doxa Dental AB.

Dernière révision: 2019-01-16

Radio-opaque
 Capsule
 Applicator

ITALIANO

1. Descrizione del prodotto

Ceramir® Bioceramic Implant Cement è un cemento permanente, radiopaco destinato alla fissaggio permanente degli impianti dentali.

È composto da zirconio, alluminio e liquido d'acqua. Il cemento, che si dura attraverso una reazione chimica, possiede delle caratteristiche di autoadesione.

Dopo Ceramir Bioceramic Implant Cement QuikCap, il cemento viene fornito nella capsula, per la sua applicazione diretta. Il volume minimo di cemento misurato dalla capsula è di 0.17 ml.

Per l'utilizzo richiesto un applicatore della capsula e un dispositivo di miscelazione sono necessari. Ceramir Applicator e Cerami Applicator 2 da Doxa Dental AB.

2. Indicazioni per l'uso

2.1 Indicazioni per la fissazione permanente

Ceramir Bioceramic Implant Cement è indicato per la fissazione permanente su supporti d'implanti.

- Restaurazioni in metallo e ceramica fusa in metallo.

