

## 3M ESPE

## RelyX™ Unicem 2 Automix

### Self-adhesive Resin Cement

### Selbstadhäsiver Composite-Befestigungszement

### Ciment de scellement composite auto-adhésif

### Cemento composito autoadesivo

### Cemento definitivo de resina autoadhesivo

### Cimento de resina auto-adesivo

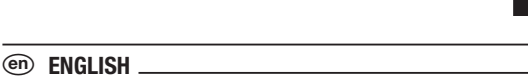


Instructions for Use  
 Gebrauchsinformation  
 Mode d'emploi



3M ESPE Customer Care/MSDS Information:
 U.S.A. 1-800-634-2249 and Canada 1-888-363-3685.

3M, ESPE, CoJet, Lava, RelyX and Sof-Lex are trademarks of 3M or 3M Deutschland GmbH. Used under license in Canada.
 © 2013, 3M. All rights reserved.



## ENGLISH

#### Product Description

RelyX™ Unicem 2 Automix is a dual-curing, self-adhesive resin cement supplied in an automix syringe. It is used for the adhesive cementation of indirect all-ceramic, composite, or metal restorations and for posts and screws. When RelyX Unicem 2 Automix is used, bonding and conditioning of the tooth structure are not necessary.

Unlike other cementation materials, RelyX Unicem 2 Automix is characterized by high stability in combination with good flowability under pressure (structural viscosity).

The cement is available in various shades.

RelyX Unicem 2 Automix contains bi-functional (meth)acrylate. The proportion of inorganic fillers is about 43% by volume; the grain size (D 90%) is about 12.5 µm. The mixing ratio, based on volume, is 1 part base paste : 1 part catalyst.

These Instructions for Use must be kept for reference for the duration of product use. Please see the pertinent information for use for details on all of the products mentioned below.

#### Indications

- Final cementation of all-ceramic, composite, or metal inlays, onlays, crowns and bridges; 2-3-unit Maryland cement and 3-unit inlay/onlay bridges (contraindicated for patients with bruxism or periodontitis)
- Final cementation of posts and screws
- Final cementation of all-ceramic, composite, or metal restorations on implant abutments
- Final cementation of Lava™ zirconia build-ups for two-piece abutments – only in accordance with the Instructions for Use for Lava™ Frame or Lava™ Plus respectively

Indications such as Maryland and inlay/onlay bridges (resin bonded bridges) demand especially high adhesive bond strength. Regardless of the manufacturer of the cement and restoration, these indications may be exposed to a higher risk of decementation. To achieve an optimal result when using RelyX Unicem 2 Automix, please refer to the sections "Tooth Preparation" and "Pre-treatment of Maryland and Inlay/Onlay Bridges".

#### Precautionary Measures

##### For Patients and Dental Personnel

- Base paste: contact with eyes may cause severe eye damage. Wear eye protection to prevent injury. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- Base paste: contains sodium persulfate that may trigger an allergic respiratory reaction in certain individuals. This product may not be appropriate for use in those individuals with known sensitivity to sulfites since a cross-reaction may occur with sodium persulfate.

#### For Patients

This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate and/or peroxide allergies.

- If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use.

#### For Dental Personnel

- This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water.
- The use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If the product contacts the glove, remove and discard the glove, wash the hands immediately with soap and water and then re-glove.
- If allergic reaction occurs, seek medical attention as needed.

3M MSDSs can be obtained from www.mmm.com, or contact your local subsidiary.

#### Precautions During Processing

- Seat temporary restorations using a eugenol-free product (e.g., with RelyX™ Temp NE). The use of temporary cements containing eugenol can inhibit the polymerization process of RelyX Unicem 2 Automix during the final cementing.
- Do not use hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) as the residues can adversely affect the adhesive strength and setting reaction of RelyX Unicem 2 Automix.

#### Pulp Protection

To avoid pulp irritation, cover areas in close proximity to the pulp by applying small amounts of hard-setting calcium hydroxide material. To avoid bite increases during the cementing of the later restoration, the pulp protection should be applied prior to taking an impression for the final restoration.

#### Tooth Preparation

##### Preparation of the Cavity/Tooth Stump

- Prior to final cementation, clean the prepared stump or the cavity thoroughly with pumice slurry, rinse with a water spray, and lightly air dry in only 2–3 bursts of water-free and oil-free air, or use cotton pellets to dry it off. Do not overdry!
  - The cavity should be just dry enough that the surface has a slightly glossy appearance. As is the case with any permanent cement, overdrying can lead to post-operative sensitivity.

Do not use substances such as desensitizers, disinfectants, astringents, dentin sealants, rinsing solutions containing EDTA, etc., after the final cleaning with pumice slurry and water. Their residues may have a detrimental effect on the bonding strength and setting reaction of the cement.

#### Preparation of Root Canals

- Treat the root canal endodontically as usual (root canal filling with gutta-percha and removal of the root canal filling, leaving 4 mm of gutta-percha apically).
- Clean the root canal with a 2.5%–5.25% solution of sodium hypochlorite (NaOCl).
- Rinse immediately with water and dry with paper points.
- We recommend the use of a rubber dam during the cementation of posts.

#### Preparation for Maryland and Inlay/Onlay Bridges

Abutment teeth must have an adequate enamel surface for bonding. They should be healthy or only slightly restored and the periodontal conditions should be good. It is the sole responsibility of the dentist to ensure proper selection of indication and technique. The guidelines of the relevant national professional associations must be observed for such indications.

- Prepare retentive elements such as circular rests and/or approximal grooves.
- Use a rubber dam and keep the cavity free of any contamination during cementation.
- Etch the enamel surface of the cavity with 37% phosphoric acid for 15–20 sec. Then rinse thoroughly with water and dry with water-free and oil-free air. In the case of exposed dentin, make sure to selectively etch the enamel to avoid post-operative sensitivity.

#### Preparatory Measures

- Remove the temporary restoration and thoroughly clean the tooth surface of any residue from the temporary cement.

- Make a trial insertion of the final restoration and check its fit and contact points.

- If a low viscosity silicone is used for the trial fit, the silicone residue must then be removed completely.
- For glass ceramic restorations, do not check the occlusion until the restoration has been cemented. Breakage could occur if done prior to being cemented in place.

- Avoid any contamination whatsoever of the surfaces to be treated during pre-treatment and until the final cementation.

#### Pre-treatment of Restorations

##### Pre-treatment of Metal Restorations

Please follow the instructions for use of the restoration material. In the absence of deviating instructions, we recommend the following procedure:

- Blast the restoration surface to be luted with aluminum oxide ≤40 µm.
- Clean the blasted surface with alcohol and dry it with water-free and oil-free air.

For Maryland and inlay/onlay bridges, please refer to "Pre-treatment of Maryland and Inlay/Onlay Bridges".

##### Pre-treatment of Etchable Glass Ceramic Restorations

Please follow the instructions for use of the restoration material. If the manufacturer has not provided deviating instructions, we recommend the following procedure:

- Use hydrofluoric acid to etch the glass ceramic restoration surface to be luted.
- Rinse thoroughly with water for 15 seconds and dry with water-free and oil-free air.
- Apply an appropriate silane in accordance with the instructions for use, e.g.:
  - RelyX™ Ceramic Primer: allow to react for 5 sec, then air dry so that the solvent evaporates completely.

**Pre-treatment of Zirconia and Aluminum Oxide Ceramic Restorations**
Please follow the instructions for use of the restoration material. If the manufacturer has not provided deviating instructions, we recommend the following procedure:

Alternative 1:

- Blast the restoration surface to be luted with aluminum oxide ≤40 µm.

- Clean the blasted surface with alcohol and dry it with water-free and oil-free air.

Alternative 2:

- Coat (silicate) the restoration surface to be luted with the micro-blasting device CoJet™ Prep and the blast-coating agent CoJet™ Sand from a distance of 2–10 mm and vertically to the surface for 15 sec, see instructions for use for CoJet Prep and CoJet Sand, respectively.
- Blow away any residues of the blasting agent with water-free and oil-free air.
- Apply an appropriate silane in accordance with the instructions for use.

For Maryland and inlay/onlay bridges, please refer to "Pre-treatment of Maryland and Inlay/Onlay Bridges".

##### Pre-treatment of Composite Restorations

Please follow the instructions for use of the restoration material. If the manufacturer has not provided deviating instructions, we recommend the following procedure:

- Blast the composite restoration surface to be luted with aluminum oxide ≤40 µm.
- Clean the blasted surface with alcohol and dry it with water-free and oil-free air.

##### Pre-treatment of Glass Fiber-reinforced Posts

Please follow the instructions for use of the post to be used. If the manufacturer has not provided deviating instructions, we recommend the following procedure:

- Clean the post with alcohol and dry it with water-free and oil-free air.
- When using RelyX™ Fiber Post application of a silane is not required. Other fiber-reinforced posts should be treated in accordance with the relevant instructions for use.

#### Pre-treatment of Implant Abutments

Please follow the recommendations for the relevant restorative material (e.g., metal, zirconia).

##### Pre-treatment of Maryland and Inlay/Onlay Bridges

Metal, Zirconia and Aluminum Oxide Surfaces:

- Coat (silicate) the restoration surface to be luted with the micro-blasting device CoJet™ Prep and the blast-coating agent CoJet™ Sand from a distance of 2–10 mm and vertically to the surface for 15 sec, see instructions for use for CoJet Prep and CoJet Sand.
- Blow away any residues of the blasting agent with water-free and oil-free air.
- Apply an appropriate silane in accordance with the instructions for use.

For etchable glass ceramics, please refer to "Pre-treatment of Etchable Glass Ceramic Restorations".

#### Times

The processing and setting times depend on the ambient and oral temperature. The times shown are based on conditions relevant for practice. As is the case with every composite cement, the setting of RelyX Unicem 2 Automix cement slows down significantly at room temperature. RelyX Unicem 2 Automix is a dual-curing cement and therefore also sensitive to natural or artificial light. The working time is significantly reduced during application under operating lights!

	min:sec
Working time from start of mixing	02:30
Light-curing in a lightwave range of 400–500 nm	
– Single surface, from occlusal	00:20
– Any other surface additional	00:20
– RelyX Fiber Post posts, from occlusal	00:40
Self-curing	
– Setting time after start of mixing	06:00

#### Application

- Select a RelyX Unicem 2 Automix syringe containing the desired color and place it ready for use.

When using a new RelyX Unicem 2 Automix syringe:

- Remove the automix syringe from the foil bag and discard the bag.
- Note down the date the syringe was removed on the syringe label.
- Remove and discard the sealing cap from the automix syringe. Check the syringe openings for blockage; remove any paste plugs.
  - The sealing cap must not be reused to close the syringe** because doing so might introduce air bubbles into the material.
- Squeeze out a small quantity of paste onto a block to equal the base paste and catalyst paste in the automix syringe. Discard the paste which has been squeezed out.

During every application:

Protect the working area from contamination with water, blood, saliva and sulcal fluid during the application and setting phase.

- Remove and discard the mixing tip remaining on the automix syringe from the previous application.
- Attach one of the two types of mixing tips ("Standard" or "Wide") and secure it by turning it to the right.
  - The mixing tip "Standard" is used without an Intraoral Tip for application in easily accessible areas.
  - The mixing tip "Wide" is used for the application with the Intraoral Tip or the Endo Tip.
- When using the mixing tip "Wide", attach an Intraoral Tip or an Endo Tip.
- Squeeze out and discard a peppercorn-size quantity of RelyX Unicem 2 Automix until an evenly mixed paste in a homogeneous color flows out of the tip.
  - The paste requires a certain amount of time to flow through the mixing tip. The flowthrough speed cannot be accelerated by increasing the pressure on the plunger.
  - As soon as the pressure on the plunger decreases, the material flow stops and the paste begins to set up. Do not use force to press out paste that has set as this could cause damage to the mixing tip and the automix syringe.
- Apply RelyX Unicem 2 Automix evenly to the entire cavity and as appropriate to the bottom side of the inlay/onlay, or fill the crown with cement.
  - Keep the opening of the mixing tip "Standard" or of the Intraoral or Endo Tip immersed in the material during the entire application to prevent the inclusion of any air bubbles.
- Seat the restoration firmly and stabilize long enough for the cement to set fully.
- Leave the used mixing tip on the automix syringe as a cap until the next application.

#### Application in the Root Canal

- See instructions under "Application" for handling of the automix syringe.
- Do not use Lentulo-Spirale to insert the cement in the root canal as this can excessively accelerate setting.
- Attach an Endo Tip to the mixing tip "Wide" for application in the root canal.
- Insert the Endo Tip as deeply as possible in the root canal and apply RelyX Unicem 2 Automix, beginning apically. Keep the tip of the Endo Tip immersed in the cement and slowly move the Endo Tip upwards as the level of the paste rises.
- Do not remove the Endo Tip from the cement until the root canal has been completely filled.
  - This so-called immersion filling should not be carried out in less than 5 sec.; this will minimize the entrapment of air bubbles.
- Place the post in the root canal filled with cement; apply moderate pressure to hold it in position. We recommend rotating the post slightly during insertion to avoid the inclusion of air bubbles.

#### Removal of Excess

Notes on oxygen inhibition: As is the case with all composite materials, RelyX Unicem 2 Automix is subject to oxygen inhibition, i.e. the upper layer (about 50 µm) which is in contact with atmospheric oxygen during the polymerization does not harden. Leaving sufficient excess permits the removal of the uncured layer during shaping/polishing without leaving behind a deficit.

#### From Restorations

Using light-curing:

- After brief curing (about 2 sec using a standard polymerization device), use a suitable instrument (e.g., scaler) to remove the excess. Larger volume excess can be removed more easily.
- Immediately light-cure after removal (see Polymerization and Shaping).

Using self-curing:

- Use a suitable instrument (e.g., scaler) to remove the excess during the self-curing phase (about 3 min after beginning the mixing in the "gel phase").
- Immediately cover the edges of the restoration with a glycerin gel to prevent oxygen inhibition.

Alternatively:

- Remove the excess before polymerization, e.g., using a sponge pellet, while using a suitable instrument to hold the restoration in position.
- Cover the edges of the restoration with a glycerin gel to prevent oxygen inhibition.
- Immediately light-cure or wait for the self-curing to finish (see Polymerization and Shaping).

#### From Posts

- Remove the cement with a suitable instrument or a cotton pellet.

#### Polymerization and Shaping

- We recommend light-curing the cement through the restoration when doing ceramic and composite work. Select the exposure times appropriate for the number of surfaces (please refer to "Times"). Polymerize the cement through the post when using transient posts. The exposure time depends on the translucency of the post being used; for RelyX Fiber Post, it is 40 sec.
- Shape any remaining uneven areas on the edges of restorations and polish the marginal area with diamond devices, aluminum oxide coated discs (e.g., Sof-Lex™), and diamond polishing paste.
- Then check the occlusion.

#### After Shaping

- Carefully check the sulcus of the treated teeth and the surrounding areas; remove any cement residues still remaining. This is especially important when cementing on implant abutments.

#### Hygiene and Disinfection

- We recommend the use of commonly available hygienic protective covering to avoid any contamination of the RelyX Unicem 2 Automix syringes during the treatment.

- Clean contaminated RelyX Unicem 2 Automix syringes with cleaning agents commonly used in the dental practice.
- Use a cloth soaked in a disinfectant commonly used in the dental practice to disinfect the automix syringe.

#### Notes

- RelyX Unicem 2 Automix can prematurely polymerize when exposed to natural or artificial lighting. Therefore avoid intensive light exposure during application.

#### Storage and Stability

Store RelyX Unicem 2 Automix in the pouch at 15°–25 °C/59°–77 °F. After removal from the pouch, use the product within 6 months and before the lapse of the expiration date. Constantly high humidity accelerates the setting and must be avoided.

#### Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

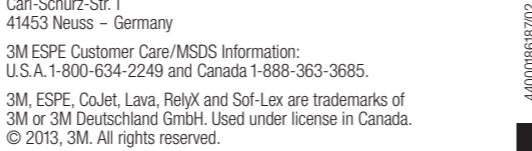
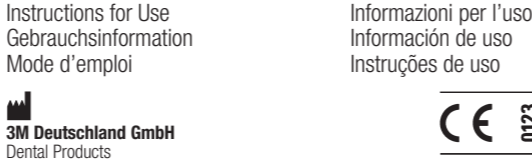
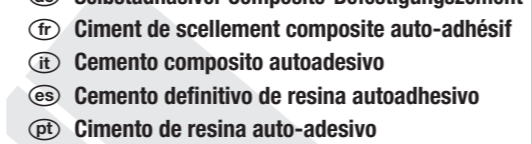
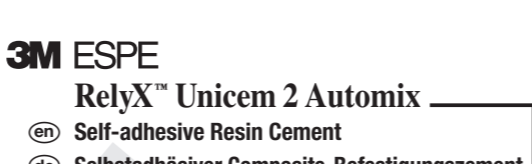
#### Warranty

3M Deutschland GmbH warrants this product will be free from defects in material and manufacture. 3M Deutschland GmbH MAKES NO OTHER WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M Deutschland GmbH's sole obligation shall be repair or replacement of the 3M Deutschland GmbH product.

#### Limitation of Liability

Except where prohibited by law, 3M Deutschland GmbH will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence, or strict liability.

Date of the information: April 2013



## FRANÇAIS

**Description du produit**
RelyX™ Unicem 2 Automix est un ciment de scellement composite universel auto-adhésif, à prise de type chémo polymérisable ou photopolymérisable (Dual), en seringue auto-mélangeuse. Il est utilisé pour le scellement par collage de restaurations indirectes entièrement en céramique, composite ou métal ainsi que pour les tenons radiculaires. L'emploi de RelyX Unicem 2 Automix rend le conditionnement de la préparation dentaire superflu. Contrairement aux autres ciments, RelyX Unicem 2 Automix se caractérise par une grande stabilité doublée d'une bonne viscosité sous pression. Le ciment de scellement est disponible en différentes teintes. RelyX Unicem 2 Automix contient des (méth-)acrylates bifonctionnels. Le taux de charges inorganiques est d'environ 43% en volume, la granulométrie (D 90 %) est d'environ 12,5 µm. Le rapport du mélange base/catalyseur est de 1:1.

Ce mode d'emploi doit être conservé pendant toute la durée d'utilisation du produit. Pour tous les détails concernant les autres produits mentionnés ci-dessous, veuillez consulter leur mode d'emploi respectif.

#### Indications

- Scellement définitif d'inlays, onlays, couronnes et bridges, entièrement en céramique, composite ou métal ; bridges collés Maryland de 2–3 éléments et bridges sur inlay/onlay de 3 éléments (contre-indiqué pour les patients souffrant de bruxisme ou de parodontite).
- Scellement définitif de tenons radiculaires.
- Scellement définitif de prothèses, entièrement en céramique, composite ou métal, sur des piliers d'implant.
- Scellement définitif de piliers implantaires Lava™ à base de zircone en deux parties – conformément au mode d'emploi de Lava™ Frame ou Lava™ Plus.

Les indications telles les bridges collés Maryland et les bridges sur inlay/onlay (bridges collés) requièrent notamment une grande force d'adhésion. Indépendamment du fabricant du ciment et de la restauration, ces indications peuvent être exposées à un plus grand risque de descellement. Pour obtenir un résultat optimal avec RelyX Unicem 2 Automix, référez-vous aux sections « Préparation de la dent » et « Traitement préalable des bridges collés Maryland et des bridges sur inlay/onlay ».

#### Précautions d'emploi

##### Pour les patients et le personnel de l'équipe dentaire

- Pâte base : le contact avec les yeux peut provoquer des lésions sévères. Porter des lunettes de protection. En cas de contact avec les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.
- Pâte base : contient du persulfate de sodium, pouvant provoquer des réactions allergiques sur le plan respiratoire chez les personnes sensibles. Ce produit ne doit pas être utilisé auprès de personnes présentant une allergie connue aux sulfites, car le persulfate de sodium est susceptible d'entraîner des réactions allergiques croisées.

#### Pour les patients

- Ce produit contient des substances susceptibles de provoquer des réactions cutanées allergiques en cas de contact. L'utilisation de ce produit chez les patients présentant une allergie connue à l'acrylique et/ou au peroxyde est vivement déconseillée.
- En cas de contact prolongé avec les muqueuses buccales, rincer abondamment à l'eau claire. En cas de réaction allergique, retirer le produit et ne plus l'utiliser ; le cas échéant, consulter un médecin.

#### Pour le personnel de l'équipe dentaire

- Ce produit contient des substances susceptibles de provoquer des réactions cutanées allergiques en cas de contact. L'utilisation de ce produit, afin de limiter le risque de réactions allergiques, éviter tout contact avec la peau, en particulier avec la pâte lors/ou elle n'est pas encore polymérisée. En cas de contact involontaire avec la peau, nettoyer immédiatement à l'eau et au savon.
- L'utilisation de gants de protection et d'une technique d'application évitant tout contact sont recommandées. L'acrylate peut traverser les gants de protection vendus dans le commerce. En cas de contact avec la pâte, retirer les gants de protection et les jeter. Se laver immédiatement les mains avec de l'eau et du savon et enlever une nouvelle paire de gants de protection.
- En cas de réaction allergique, consulter un médecin.

Vous pouvez vous procurer les fiches de sécurité 3M MSDSs sur le site Internet www.mmm.com ou auprès de votre filiale locale.

#### Précautions d'emploi lors de la préparation

- Sceller les restaurations provisoires avec un produit ne contenant pas d'eugénil (par exemple RelyX™ Temp NE). L'utilisation de matériaux de scellement provisoire contenant de l'eugénil peut inhiber le processus de polymérisation de RelyX Unicem 2 Automix lors du scellement définitif.
- Prière de ne pas utiliser de peroxyde d'hydrogène (H<sub>2</sub>O<sub>2</sub>), les résidus étant susceptibles de nuire à l'adhésion et à la prise de RelyX Unicem 2 Automix.

#### Protection pulpaire

Afin de prévenir les irritations pulpaires, il est conseillé de recouvrir ponctuellement les zones juxtapulpairees de la préparation avec un matériau à base d'hydroxyde de calcium durcissant lors de sa prise. Afin d'éviter une sur-occlusion lors du scellement de la prothèse, la protection pulpaire doit être appliquée avant de procéder à la prise d'empreinte pour la réalisation de la prothèse définitive.

#### Préparation de la dent

##### Préparation de la cavité/de la préparation dentaire

- Avant le collage définitif, nettoyer soigneusement le moignon dentaire préparé ou la cavité avec un mélange d'eau et de pierre ponce, rincer avec un spray d'eau puis sécher avec seulement 2 ou 3 jets d'air courts et exempts d'eau et d'huile ou boudard avec une bouslette de coton avant de procéder au scellement définitif. Ne pas sécher excessivement !
  - La cavité doit être juste assez sèche pour présenter une surface sèche. Comme pour tout ciment de scellement, un séchage excessif peut contribuer à l'apparition de sensibilités post-opératoires.

Il est déconseillé d'utiliser d'autres substances telles que des agents désensibilisants, des désinfectants, des astringents, des vernis isolants dentinaires, des solutions de rinçage à base d'EDTA, etc. après le nettoyage final à l'aide d'une pâte à base de pierre ponce et d'eau. Les résidus de ces substances peuvent nuire à l'adhésion et à la prise du ciment de scellement.

#### Préparation des canaux radiculaires

- Traiter le canal radiculaire de manière endodontique comme d'habitude (obturation du canal radiculaire avec de la gutta-percha et retrait de l'obturation du canal radiculaire en laissant 4 mm de gutta-percha apical-ement).

- Nettoyer le canal radiculaire avec une solution d'hypochlorite de sodium (NaOCl) à 2,5 %–5,25 %.
- Immédiatement après, rincer avec de l'eau puis sécher avec des cônes de papier.
- Lors du scellement des tenons radiculaires, il est recommandé de placer la digue.

##### Préparation des bridges collés Maryland et des bridges sur inlay/onlay

Les dents piliers des bridges collés doivent avoir une surface d'émail adaptée au collage. Elles doivent être saines ou légèrement restaurées et les conditions partiales doivent être bonnes. Il est de la responsabilité du dentiste de s'assurer du bon choix des indications et des techniques. Les directives des associations professionnelles nationales à ce sujet doivent être consultées pour ce type d'indications.

- Préparer les éléments de rétention comme les appuis cing