



GTIN: 7640178010802
#SMT-3084

Medi-Zirconia II

Dual Cure Self Adhesive Resin Cement

INSTRUCTIONS FOR USE

I. INTRODUCTION

Medi Zirconia II is a dual-cure (light- and/or self-cure), fluoride releasing, radiopaque self-adhesive resin cement for ceramic (porcelain, zirconia, etc.), composite resin, and metal restorations. It is supplied in an automix delivery system which can mix equal amounts of two components.

II. INDICATION

- [1] Cementation of crowns, bridges, inlays and onlays
- [2] Cementation of prosthetic restorations on implant abutments and frames
- [3] Cementation of adhesion bridges and splints
- [4] Cementation of posts and cores
- [5] Amalgam bonding

III. CONTRAINDICATION

Patients with a history of hypersensitivity to methacrylate monomers

IV. POSSIBLE SIDE EFFECTS

The oral mucosal membrane may turn whitish when contacted by the product due to the coagulation of protein. This is usually a temporary phenomenon that will disappear in a few days. Instruct patients to avoid irritating the affected area while brushing.

V. INCOMPATIBILITY

Do not use eugenol containing materials for pulp protection or temporary sealing, since the eugenol could retard the bonding system curing process.

VI. PRECAUTIONS

1. Safety precautions

1. Avoid use of the product for patients with a history of hypersensitivity to methacrylate monomers.
2. If any hypersensitivity occurs, such as dermatitis, discontinue use of the product and consult a physician.
3. Wear gloves or take other appropriate protective measures to prevent the occurrence of hypersensitivity that may result from contact with methacrylate monomers.
4. Use caution to prevent the product from coming in contact with the skin or getting into the eye. Before using the product, cover the patient's eyes with a towel to protect the patient's eyes from splashing material.
5. If the product comes in contact with human body tissues, take the following actions:

Contact with eye:

Immediately wash the eye with copious amounts of water and consult a physician.

Contact with skin:

Immediately wipe it off with a cotton pledget moistened with alcohol or gauze and wash with copious amounts of water.

6. Use caution to prevent the patient from accidentally swallowing the product.

7. Avoid looking directly at the dental curing unit when curing the product.

2. Handling and manipulation precautions

1. Do not use the product in conjunction with the other composite resins. Mixing materials may cause a change in physical properties, possibly a decrease, from the properties expected.
2. When light curing the product, note the depth of cure in this instructions for use.
3. The product polymerize under an operating light or natural light (sunlight from windows). Avoid operating light or natural light, and use within 5 minutes from dispensing.
4. The emitting tip of the dental curing unit should be held as near and vertical to the resin surface as possible. If a large resin surface is to be light cured, it is advisable to divide the area into several sections and light-cure each section separately.
5. Low intensity of light causes poor adhesion. Check the lamp for service life and the dental curing unit guide tip for contamination. It is advisable to check the dental curing light intensity using an appropriate light evaluating device at appropriate intervals.
6. The use of the product is restricted to a licensed dental professional.

3. Storage precautions

1. Do not use after the expiration date. Note the expiration date on the outside of package.
2. Keep away from extreme heat or direct sunlight.
3. The product must be stored at 2-8°C/36-47°F when not in use.
4. Replace the cap as soon as possible after the composite has been dispensed from the syringe.
5. The product must be stored in proper places where only dental practitioners can access it. **VI. COMPONENTS**

1) Components Please see the outside of the package for contents and quantity.

2) Ingredients Principal ingredients:

- Silanated silica filler
- Silanated barium glass filler
- Bisphenol A diglycidylmethacrylate (Bis-GMA)
- Triethyleneglycol dimethacrylate
- di-Camphorquinone

The total amount of inorganic filler is approx. 67 vol%.

1.Shades

Medi Zirconia II is available in the following 3 shades; Universal (A2), Translucent or White.

2. Components

Please see the outside of the package for contents and quantity.

- 1) Paste A and B: Universal (A2), Translucent or White
- 2) Accessories

- Mixing tip
- Endo tip (SS)

3. Ingredients

- (1) Paste A
 - 10-Methacryloyloxydecyl dihydrogen phosphate (MDP)
 - Bisphenol A diglycidylmethacrylate (Bis-GMA)
 - Triethyleneglycol dimethacrylate (TEGDMA)
 - Hydrophobic aromatic dimethacrylate
 - 2-Hydroxymethylacrylate (HEMA)
 - Silanated barium glass filler
 - Silanated colloidal silica
 - di-Camphorquinone
 - Peroxide
 - Catalysts
 - Pigments
- (2) Paste B
 - Hydrophobic aromatic dimethacrylate
 - Hydrophobic aliphatic dimethacrylate
 - Silanated barium glass filler
 - Surface treated sodium fluoride
 - Accelerators
 - Pigments

The total amount of inorganic filler is approximately .40 vol%. The particle size of inorganic fillers ranges from 0.02 µm to 20 µm

VII. CLINICAL PROCEDURES

1. Cleaning tooth structure

- [1] Cementation of crowns, bridges, inlays and onlays
- [2] Cementation of prosthetic restorations on implant abutments and frames

- [3] Cementation of adhesion bridges and splints

A-1. Conditioning the cavity / tooth stump, prosthetic frame and implant abutment surfaces

- (1) When cementing in the oral cavity, remove the temporary sealing material and temporary cement in the usual manner, and clean the cavity using moisture control.
- (2) Trial fit the prosthetic restoration to check its fit on the cavity, stump (tooth, metal, composite), frame or implant abutment.

Treatment of enamel

When cementing to uncut enamel or using with adhesion bridges, apply Etchant (**Medi Etch 37% Syringe**) to the enamel surface and leave for 10 seconds, then rinse and dry the surface.

A-2. Conditioning the prosthetic restoration surface

Please follow the Instructions for Use of the restoration material. In the absence of specific instructions, we recommend the following procedure:

If the adherent surface is metal, metal oxide ceramic (such as zirconia) or composite resin

Roughen the adherent surface by blasting with 30 to 50 µm alumina powder at an air pressure of 0.1-0.4 MPa. The air pressure should be properly adjusted to suit the material and/ or shape of the prosthetic restoration, using caution to prevent chipping. After blasting, clean the prosthetic restoration by using an ultrasonic cleaning unit for 2 minutes followed by drying it with an air stream. Be sure the cavity is adequately cleaned. An adequately cleaned cavity assures maximum adhesive performance.

After blasting and cleaning, for optimum performance when using hybrid ceramics or composite resin, apply a phosphoric acid Etchant (**Medi Etch Gel 37% Syringe**), leave for 5 seconds, and then rinse and dry. Then apply a silane

coupling agent (**Medi Silane**) according to the instructions for use.

Preparing the syringe and accessories

Attach a mixing tip or an endo tip to the syringe in the usual manner. Before attaching a mixing tip or an endo tip, extrude small amounts of the two pastes, making sure equal amounts are being dispensed through the two outlets of the syringe, and discard them. If equal amounts of paste are not used, there is a possibility of poor polymerization.

- After use, the syringe should be stored with the cap. When you put the cap back on the syringe before storage, make sure the cap is free of paste.
- When replacing an old mixing tip and endo tip with a new one, turn it 1/4 of a turn counterclockwise to align the projections of the mixing tip or the endo tip with the grooves in the syringe. Remove it from the syringe by twisting and pressing downward.
- If the paste has hardened making it difficult to squeeze the mixed paste out of the syringe, remove hardened paste by using an appropriate instrument.

• When changing the direction of the endo tip, rotate the distal attachment and use caution not to bend the slender dispensing portion of the tip.

A-4. Cementing the prosthetic restoration

(1) Apply the mixed paste over the entire adherent surface of the prosthetic restoration or the entire tooth surface within the cavity. If the paste is applied directly on the entire cavity / tooth stump or implant abutment intra-orally, you must begin step (2) within 40 seconds after application of the paste.

(2) Place the prosthetic restoration on the cavity / tooth stump, prosthetic frame or implant abutment.

[CAUTION]

When dispensing the cement intra-orally using the mixing tip or endo tip, be careful to avoid cross-contamination. Cover the entire syringe with a disposable barrier (e.g. a poly bag) to prevent saliva and blood contamination. Disinfect the syringe by wiping it with an absorbent cotton with alcohol both before and after use.

A-5. Removing the excess cement

Remove any excess cement using either of the following two methods:

Light-curing

Light-cure any excess cement in several spots for 2 to 5 seconds. Holding the prosthetic restoration in position, remove the tack-cured excess cement using a dental explorer. It is advisable to determine in advance the light-curing time of the excess cement by light-curing some paste on a mixing pad.

Chemical-curing

Leave any excess cement for 2 to 4 minutes after placement of the prosthetic restoration. Remove the tack-cured excess cement using a dental explorer.

[CAUTION]

When removing the excess cement after tack-curing, hold the restoration in place to avoid the possibility of lifting the restoration, since there could be some insufficiently cured resin cement. If dental floss is used to remove the excess cement, it should be used in the direction that does not lift the prosthetic restoration.

A-6. Final curing

Finally, cure the cement using either of the following two methods:

Prosthetic restorations that are not translucent (e.g. metal crowns):

Allow the cement to chemical-cure by letting it set for 5 minutes after placement of the prosthetic restoration.

Prosthetic restorations that are translucent (e.g. ceramic inlays):

Light-cure the entire surface and margins of the prosthetic restoration using the dental curing unit. If the area you want to light-cure is larger than the light emitting tip, divide the exposure process into a few applications.

Please confirm the curing time by referencing the following table:

Table: Curing time for type of light source.

Type of light source (Light intensity)	Curing time
High Intensity Blue LED (More than 1500mW/cm2)	10 sec.
Blue LED (800-1400 mW/cm2)	15 sec.

The effective wavelength range of each dental curing unit must be 400 - 515 nm.

* Peak of emission spectrum: 450 - 480 nm

Table: Working time and setting time (for cementation of crowns, bridges, inlays, onlays and adhesion bridges)

Working time after initial dispensing(25°C)	1min.
Working time after insertion of the paste into the cavity	40 sec.
Tack-curing for removal of excess cement	
Light-Cure (LED)	2-6 sec.
Self-Cure (37°C)	2-5 min.
Final Curing after placement of the restoration	
Light-Cure (LED)	10 sec.
Self-Cure (37°C)	6 min.

Curing time by using BLUE LED (light intensity: 1500 mW/cm2)

Standard procedure II (Indications [4])

- [4] Cementation of post and cores

B-1. Preparing a cavity and trial fit of the core or post

(1) Prepare the endodontically filled root canals for post/ core placement in the usual manner. Provide moisture control with a rubber dam.

(2) Trial fit a core or a dental post of appropriate thickness into the prepared cavity. Cut and trim the post as necessary. Wipe away any contamination from the surface of the core or post using a piece of gauze or a cotton pad soaked with ethanol.

B-2. Blasting the core or post

Blast the core or post surface according to step "A-2. Conditioning the prosthetic restoration surface". Do not blast glass fiber posts due to potential damage.

B-3. Preparing the syringe and accessories

See section "A-3."

B-4. Placing the core or post

(1) Apply the mixed paste over the entire adherent surface of the core or post, or the entire tooth surface within the cavity. If the paste is applied directly into the cavity, you must begin step (2) within 40 seconds after application of the cement.

(2) Place the core or post quickly into the cavity, slightly vibrating it to prevent air bubbles from entering the root canals.

B-5. Spreading the excess cement

Using a disposable brush tip, spread the excess paste over the coronal base and post head.

B-6. Light-curing

Light-cure the margins of the core or post. See table "Curing time for type of light source" in A-6.

B-7. Preparing for the final restoration

For cores Seat the core in place for approximately 10 minutes and make sure the cement has been completely cured before preparing the abutment tooth.

For dental posts

After placing the dental post, place the core build-up composite resin according to the Instructions for Use.

Prepare the abutment tooth 10 minutes after placing the dental post.

C. Standard procedure III (Indications [5])

- [5] Amalgam bonding

C-1. Cleaning of tooth structure

Clean the cavity and provide moisture control in the usual manner.

C-2. Preparing the syringe and accessories

See section "A-3."

C-3. Placing the amalgam

(1) Apply the mixed paste over the entire tooth surface within the cavity. You must begin step (2) within 40 seconds after application of the cement.

(2) The triturated amalgam should be condensed on the unset mixed paste. Occlusal carving can be accomplished in the usual manner.

[CAUTION]

When dispensing the cement intra-orally using the mixing tip or endo tip, be careful to avoid cross-contamination. Cover the entire syringe with a disposable barrier to prevent saliva and blood contamination. Disinfect the syringe by wiping it with an absorbent cotton with alcohol both before and after use.

C-4. Removing the excess cement

Any excess paste remaining at the margins can be removed by Light-curing or chemical-curing (refer to section "A-5").

C-5. Final curing

Allow the cement to chemical-cure by letting it set for 5 minutes after placement of the Amalgam or light-cure the margins of Amalgam using the instruction for the dental curing unit (refer to section "A-6"). If the area you want to light-cure is larger than the light emitting tip, divide the exposure process into a few applications.

[CAUTION]

Federal (U.S.A.) law restricts this device to sale by or on the order of dental professionals.

[WARRANTY]

Swissmeditec GmbH will replace any product that is proven to be defective. Swissmeditec GmbH 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.



Reference Number



Keep away from sunlight



Refer to instruction manual



Keep Dry



Storage temperature range



Expiry date



Date of Manufacture



Manufactures address



SwissMediTec GmbH

Businesspark
Bahnhofstrasse 42
6162 Entlebuch
Switzerland

Tel.:+41 41 481 00 86
+41 79 482 32 98

www.swiss-meditec.ch

Email:info@swiss-meditec.ch