

ZIRCULES™ INSTRUCTIONS FOR USE

ZIRCONIA NANO-FILLED CORE MATERIAL

ZIRCULES is a dual-cure highly radiopaque flowable hybrid composite material with nano particles (nano zirconium dioxide, nano calcium fluoride) for core build-up and cementation of posts. Due to its excellent mechanical properties, final crown preparation can be carried out more precisely. ZIRCULES is based on poly- and difunctional methacrylates and inorganic filler particles of 0.02-10 µm. The total filler content is 64% by weight and 48% by volume. Delivered in 1:1 automix cartridges or 1:1 mini-mix syringes, ZIRCULES can be easily dispensed and applied directly. ZIRCULES exhibits a short setting time without high heat generation. Its dual-cure properties enable ZIRCULES to be used as both a cement as well as a core build-up material in cases where a light-curing is not guaranteed to be sufficient.

ZIRCULES meets the requirements of DIN EN ISO 4049.

INDICATIONS

Material for core build-ups and cementing of posts.

CONTRAINDICATIONS

The placement of ZIRCULES is contraindicated if a dry working area or the recommended application technique are not possible. Also, do not use ZIRCULES if the patient is known to be allergic to any of the ingredients.

SIDE EFFECTS

In singular cases, ZIRCULES may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used. Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of calcium hydroxide material.

INCOMPATIBILITY WITH OTHER MATERIALS

Do not use in combination with substances containing eugenol, as eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol-containing products, nor let the composite allow coming into contact with materials containing eugenol.

PREPARING THE AUTOMIX CARTRIDGE

Take off the turn cap of the cartridge and throw it away (do not re-use). Place on a 1:1 mixing tip by attaching it with a sideways turning movement, locking the mixing tip in place. Load the cartridge into the gun. ZIRCULES is now ready for use.

PREPARING THE MINI-MIX SYRINGE

Remove the cap of the mini-mix syringe and throw it away (do not re-use). Place on a 1:1 mixing tip. Turn the tip 90° until it locks into position. The material is now ready for use.

Note: Always discard the first "pea size" amount or 2-3mm of ZIRCULES (repeat this step with every new mixing tip).

Store used cartridge with used mixing tip attached in the dark.

The working time (23°C/74°F) of ZIRCULES in the self-cure mode is 1:30 minutes from the start of mix.

POST CEMENTATION

ISOLATION

Use of a rubber dam to isolate the tooth is strongly recommended.

ROOT CANAL PREPARATION

Refer to directions of the selected post manufacturer. Remove all existing restorations and decay from the tooth. Prepare and clean the root canal with sodium hypochlorite, rinse and remove excess solution from the canal with a paper point.

Condition and apply a bonding agent according to the manufacturer's instructions.

The total-etch technique with H₃PO₄ and subsequent application of an appropriate bonding agent is recommended. If using a self-etch technique, please refer to manufacturer's instructions for use.

POST CEMENTATION

Prepare the selected post according to manufacturer directions. ZIRCULES is extruded into the prepared root canal and onto the post. Seat the post carefully into the canal and maintain firm pressure until the post is seated. ZIRCULES self-cures within 3:30 minutes. For post stabilization, light-cure the coronal portion of the cemented post for 20 seconds with a curing light (wavelength range 400-500 nm) with a light intensity of at least 1000mW/cm².

As soon as ZIRCULES has set, proceed with core build-up.

CORE BUILD-UP

ISOLATION

Use of a rubber dam to isolate the tooth is strongly recommended.

CAVITY PREPARATION

Remove all existing restorations and decay from the tooth. If necessary, place any pins or posts. Refer to directions of the selected post manufacturer.

PULP PROTECTION

The cavity floor of deep excavations should be covered with a thin layer of hard setting calcium hydroxide material.

APPLICATION OF A BONDING AGENT

Condition and apply a bonding agent according to the manufacturers' instructions.

The total-etch technique with H₃PO₄ and subsequent application of an appropriate bonding agent is recommended. If using a self-etch technique, please refer to manufacturer's instructions for use.

APPLICATION

Place the mixing tip directly into the preparation and press out the paste.

ZIRCULES is automatically mixed when dispensed with slight and even pressure. Filling should occur from the bottom up to prevent voids. To facilitate placement of ZIRCULES, place a matrix band around the prepared tooth.

ZIRCULES may be contoured by using a composite instrument. A flat-ended interproximal carver is recommended.

Place ZIRCULES directly into the preparation and allow it to self-cure for 3:30 minutes. After, the material should be light-cured (40 seconds) with a curing light (wave length range 400-500 nm) with an light intensity of at least 1000mW/cm². With this technique, optimal physical properties will be obtained.

An explorer can be used to test that ZIRCULES has completely set. Remove the matrix only after the material has set.

Final crown preparation on ZIRCULES can be finished by using crown preparation burs.

ADDITIONAL NOTES:

- Do not use any resin to adjust the viscosity of the composite restorative material.
- Do not use in combination with substances containing eugenol as eugenol can impair the hardening of the composite and causes discoloration. Do not store the composite material in proximity of eugenol-containing products, nor let the composite come in contact with materials containing eugenol.
- Contact of resin pastes with skin and gingival tissue should be avoided, especially by anyone having known resin allergies.

STORAGE

Do not store above 20°C/68°F. Store unopened material in the refrigerator. Open cartridges should be used up within 3 months. Do not use after expiration date.

KEEP AWAY FROM CHILDREN FOR DENTAL USE ONLY

WARRANTY:

Clinician's Choice Dental Products warrants this product will be free from defects in material and manufacture. Clinician's Choice Dental Products 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 the user's application. If this product is defective within the warranty period, your exclusive remedy and Clinician's Choice Dental Products' sole obligation shall be repair or replacement of the product.

LIMIT OF LIABILITY:

Except where prohibited by law, Clinician's Choice Dental Products 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.

For questions or comments, please call:

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SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION/PREPARATION/COMPANY UNDERTAKING

Trade Name: ZIRCULES Zirconia Nano-Filled Core Material
Clinician's Choice Dental Products Inc.

167 Central Avenue, London, ON, Canada, N6A 1M6

For U.S. Distribution: Brookfield, CT, USA, 06804

Emergency Information: 1-800-265-3444, (519) 641-3066, (8:00am ET - 5:00pm ET)

Prepared By: Peter G. Jordan

2. HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification According to Regulation (EC) No 1272/2008:

Skin Irrit. 2, H315 Causes skin irritation

Eye Irrit. 2, H319 Causes serious eye irritation

Skin Sens. 1; H317 May cause allergic skin reaction

INFORMATION CONCERNING PARTICULAR HAZARDS FOR HUMAN AND ENVIRONMENT

The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

LABEL ELEMENTS

Labeling According to Regulation (EC) 1272/2008:



Signal word

Warning

Hazard statements

H315 Causes skin irritation

H319 Causes serious eye irritation

H317 May cause allergic skin reaction

PRECAUTIONARY STATEMENTS

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 If In Eyes: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

P302+P352 If On Skin: Wash with plenty of soap and water.

Labeling according to EU guidelines: Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

OTHER HAZARDS

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

3. COMPOSITION/INFORMATION OF INGREDIENTS

CHEMICAL CHARACTERIZATION:

Description: Mixture of poly- and difunctional methacrylates, barium glass filler, nano-zirconiumdioxide, nano-calciumfluoride, initiator, catalyst, stabilizer.

Hazardous Components: Methacrylates GHS07, H315, H319, H317, H335

4. FIRST-AID MEASURES

General Information: Seek medical advice, if symptoms occur, which can be caused by the product.

After Skin Contact: Wash with plenty of water and soap.

After Inhalation: Fresh air

After Eye Contact: Rinse with plenty of water and consult a doctor.

After Swallowing: If symptoms persist, consult a doctor.

5. FIRE FIGHTING MEASURES

Extinguishing Media: CO₂, powder, water spray.

Use extinguishing method and media suitable to surrounding fire.

Special Hazards Arising From The Substance or Mixture: No further relevant information available.

Protective equipment: Wear self-contained respiratory protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Not required

Environmental Precautions: Do not allow to enter drains/surface water/ground-water.

Methods for Cleaning Up: Pick up mechanically. Clean up affected area.

Reference To Other Sections:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7. HANDLING AND STORAGE

Handling: This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Information For Safe Handling: Observe normal care for working with chemicals.

Information About Fire And Explosion Protection: No special measures required.

Storage: Store in a dry place. Store tightly closed. Storage temperature <20°C.

Requirements At Storerooms And Containers: Store only in the original containers.

Further Information On Storage Conditions: Store away from food.

Specific End Uses: No further relevant information available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components With Limits Of Values To Be Supervised At The Workplace: The product contains no relevant quantities of components with limits of values to be supervised at the workplace.

Additional Information: The lists valid during the making were used as basis.

PERSONAL PROTECTIVE EQUIPMENT:

General Protective And Hygienic Measures: The usual precautionary measures are to be adhered to when handling chemicals. Keep away from food and beverages. Avoid contact with eyes or skin.

Hand protection: Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: Safety glasses

Respiratory protection: Required, when aerosols are generated.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

APPEARANCE:

Form: Flowable paste

Color: Tooth colored

Odor: Odorless

SAFETY RELEVANT BASIC DATA:	Value	Unit	Measure
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Melting point/melting range:	n.a.		
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Boiling point/boiling range:	n.a.		
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Flash point:	n.d.		
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Ignition temperature:	n.d.		
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Danger of explosion:	none		
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Density:	1.75 (20°C)	g/cm3	
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Vapor pressure:	n.a.		
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pH:	Neutral		
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Solubility in/miscibility with:	Partially soluble in toluene, silicone oil		
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Water:	Insoluble		
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Content of solvents:	none		
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Organic solvents:	none		
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10. STABILITY AND REACTIVITY

THERMAL DECOMPOSITION / CONDITIONS TO AVOID

Possibility Of Hazardous Reactions: No information available.

Conditions to Avoid: Heat, direct sunlight and radical starters. The product is stable by proper use. Avoid contact with alkali metals, hydrides, strong oxidizing agents, radical initiators.

Hazardous Decomposition Products: No information available.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: No data available

PRIMARY IRRITATION:

Skin: Irritant

Eye: Irritant

Sensitization: Sensitization by skin contact possible

Additional Toxicological Information: Allergic reactions to the product after long-term exposure are possible. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12. ECOLOGICAL INFORMATION

General Information: Avoid transfer into environment

Classification of Water Endangerment: WGK=1 (slightly polluting substance).

13. DISPOSAL CONSIDERATION

PRODUCT:

Recommendation: Small quantities can be disposed of with household waste. Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

UNCLEANED PACKAGING:

Recommendation: Disposal must be made according to official regulations.

14. TRANSPORT INFORMATION

Land Transport ADR/RID And GGVS/GGVE (Germany): Not subject to transport regulations.

Sea Transport IMDG: Not subject to transport regulations.

Air transport ICAO-TI and IATA-DGR: Not subject to transport regulations.

15. REGULATORY INFORMATION

Classification According To EC-Guidelines: The product is a medical device according to EC-directive 93/42 EEC.

Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16. OTHER INFORMATION

Changes Compared With The Previous Version: Adaptation according to 1907/2006/EG, Article 31.

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data does not signify any warranty with regards to the product's properties. However, users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.