

ZIRC-ULES INSTRUCTIONS FOR USE

ZIRCONIUM NANO-FILLED CORE MATERIAL

ZIRC-ULES 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. Delivered in 1:1 automix cartridges or 1:1 mini-mix syringes, ZIRC-ULES can be easily dispensed and applied directly. ZIRC-ULES exhibits a short setting time without high heat generation. Its dual-cure properties enable ZIRC-ULES 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.

ZIRC-ULES meets the requirements of DIN EN ISO 4049.

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. ZIRC-ULES 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 ZIRC-ULES (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 ZIRC-ULES 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. ZIRC-ULES 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. ZIRC-ULES self-cures

within 3:30 minutes. For post stabilization, light-cure the coronal portion of the cemented post for 20 seconds.

As soon as ZIRC-ULES 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.

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

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

Place ZIRC-ULES directly into the preparation and allow it to self-cure for 3:30 minutes. After, the material should be light-cured (40 seconds). With this technique, optimal physical properties will be obtained.

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

Final crown preparation on ZIRC-ULES 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.

CE
0543

**KEEP AWAY FROM CHILDREN
FOR PROFESSIONAL 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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MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION/PREPARATION/COMPANY UNDERTAKING

Trade Name: ZIRC-ULES Zirconium Nano-Filled Core Material

Company: 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

Initial Revision: March 2011

2. HAZARDS IDENTIFICATION

Risk Identification:

Special Risks for Human Beings and Environment: None

Classification: Classification corresponds to actual EEC guidelines, however completed with details from technical literature and company data.

3. COMPOSITION/INFORMATION OF INGREDIENTS

Chemical Characterization: Mixture of poly and difunctional methacrylates, barium glass filler, nano-zirconiumdioxide, nano-calcium fluoride, initiator, catalyst, stabilizer

Description:

Hazardous Components: None

CAS-Nr: Name: Classification:

4. FIRST-AID MEASURES

General Information:

After Skin Contact: Wash with plenty of water and soap

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

After Swallowing: Seek medical advice immediately

5. FIRE FIGHTING MEASURES

Extinguishing Media: CO₂, water

Protective Equipment: Not necessary

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Not necessary

Environmental Precautions:

Methods for Cleaning Up: Wipe up with absorbent material

Additional Information:

7. HANDLING AND STORAGE

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

Handling Procedures: No procedures, if correctly handled

Recommendation for Fire and Explosion Protection:

Storage: Store in dry places (<20°C). Store away from food.

Requirements for Storerooms and Containers:

Requirements for Storage with Other Products:

Additional Storage Conditions:

Storage Classification:

VBF-Classification:

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Additional Information for Technical Plants:

Components with Limits of Values to be Supervised at the Workplace:

CAS-Nr.	Name	Art	Value	Unit
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The product contains no relevant quantities of components with limits of values to be supervised at the workplace.

Additional Information:

Personal Protective Equipment: Not necessary

General Measures of Protection and Hygiene:

Normal hygienic measures

Respiration:

Hands:

Eyes:

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form: Flowable paste

Color: Different

Odor: Odorless

INFORMATION ON CHANGE

IN THE PHYSICAL STATE	Value	Unit	Measure
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Melting Point/Melting Range: N/A

Boiling Point/Boiling Range: N/A

Flash Point: N.D.

Autoignation Temperature: N.D.

Danger of Explosion: None

Density: 1.75 g/cm³

Vapor Pressure: N/A

Viscosity: N.D. (flowable paste)

pH: N/A

Solubility in/Miscibility with: Slightly in toluene

Water: Insoluble

Content of Solvents: None

Organic Solvents: –

Water: –

Content of Solids: None

10. STABILITY AND REACTIVITY

Incompatibility with other Substances: Peroxides, Metal Powders, Strong Oxidizers, Free Radical Initiators

Hazardous Decomposition Products: Not known

11. TOXICOLOGICAL INFORMATION

Allergic reaction to methacrylate by chronic exposure to product is possible.

Acute Toxicity:

Primary Irritation:

Skin: Contact: X

Skin Absorption: ND

Eye: Irritating

Inhalation: Non-volatile

Ingestion: Possibly toxic if swallowed

Sensitization of Product: Not observed

Additional Toxicological Information: During the long period of use as a composite material for dental purposes, no health diseases have been reported.

12. ECOLOGICAL INFORMATION

General Information: No data known

Classification of Water Endangerment:

13. DISPOSAL CONSIDERATION

Product:

Recommendation: Use proper landfill disposal or incineration in accordance with local, state and federal regulations

Disposal Key Number:

Uncleaned Packaging:

Recommendation:

14. TRANSPORT INFORMATION

Land Transportation ADR/RID: Not classified as dangerous goods

Sea Transport IMDG: Not classified as dangerous goods

Air Transport CAO, PAX: Not classified as dangerous goods

15. REGULATORY INFORMATION

Classification according to EEC Guidelines: No classification necessary to actual EEC Guidelines

National Prescriptions:

Classification According to VbF: N/A

16. OTHER INFORMATION

Changes compared with the previous version: Adaptation according to REACH regulation (EC) No. 1907/2006

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.