



Safety and Clinical Performance Summary

The Summary of Safety and Clinical Performance (SSCP) aims to provide public access to an up-to-date summary of the main aspects of the safety and clinical performance of the device.

The following information is intended for user's/health professionals.

The SSCP is not intended to replace the Instructions for Use as the primary document to ensure safe use of the device, nor to provide diagnostic or therapeutic suggestions to intended users or patients.

1. Device Identification and General Information

1.1 Trade name(s) of the device(s)

TEMPORARY CEMENTS WITH EUGENOL

- Medental Root Canal Sealer
- Medental Z.O.E. Cement Type I
- Medental Z.O.E. Cement Type III
- Medental Multi-Purpose Z.O.E. Cement
- Medental Surgical Dressing Cement
- Medental Z.O.E. Cement Type I Fast Setting

1.2 Name and address of the manufacturer

CONAMCO, S.A. de C.V.

José María Bustillos No. 28 Bis, 1er y 2do. piso. Colonia Algarín, Delegación Cuauhtémoc, CP.
Ciudad de México, 06880, Mexico

1.3 Manufacturer's Unique Registration Number (SRN)

MX-MF-000020252

1.4 Basic UDI-DI

750229184268624 This basic UDI-DI is only relevant for EU-MDR/2017-745.

1.5 Description/text of medical device nomenclature

Term	Definition
Temporary Cements with Eugenol	Z.O.E. Cements are a family of products made with Zinc oxide powder and Eugenol liquid. Eugenol is the essence of cloves. ZOE cements are generally used as temporary cements with expected duration. (MDR 2017/745. See Annex VIII 1.3 "long term". [Chapter III, Rule 5, point 3]) Of use from one week to four months but also, they can be used as definitive cements. are some of the most frequently examined teeth, as the size, shape and color of the upper anterior teeth play an important role in dental aesthetics and the aesthetics of the smile.



Anterior teeth	
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1.6 Device class

Class IIa

1.7 Year in which the first (CE) covering the device was issued

MAY 19th, 2010

1.8 Authorized Representative; name and SRN

Ivonne Richaud / Travessera de Gracia 315, 2° - 1°, Barcelone, CP. 08025, Spain.

SRN: ES-AR-000017547

1.9 NB name and unique NB identification number

Intertek Medical Notified Body AB

ID Number 2862

2. Intended use of the device

2.1 Intended purpose

The TEMPORARY CEMENTS WITH EUGENOL only can be used directly on the teeth, for temporary and intermediate cementation and filling and Surgical Dressing Cement is the only temporary cement that is in contact with soft tissue (gums) as a Bandage.

2.2 Indication(s) and target population(s)

a. **Type I Z.O.E.** Is temporary cement for the purpose of protecting dental pulp for a short time or temporary restoration cement.

b. **Z.O.E. Type I** Temporary Fast Setting. Is temporary cement for the purpose of protecting dental pulp for a short time.

c. **Type III ZOE cement** is the longest lasting Z.O.E. temporary cement. It is reinforced with acrylic powder.

d. **Z.O.E. Surgical Dressing cement** is made by reinforcing the liquid eugenol with resins and oil made out Zinc oxide to produce a convenient coverage system which sets slowly for post oral surgery. Does not contain asbest.

e. **Z.O.E. Root Canal Sealer cement** is a zinc oxide eugenol cement with a powder reinforcement and barium sulfate to make it radiopaque.

f. **Multi-purpose Temporary Cement Z.O.E.:** Dressing/surgical to serve as a protective covering over operated or treated areas to prevent contact with irritating or infecting substances.



Population (s)

All patients of any age, gender, weight, or ethnicity, with permanent dentition, who, for different reasons, must be make restorations with Medental TEMPORARY CEMENTS WITH EUGENOL.

2.3 Contraindications

The TEMPORARY CEMENTS WITH EUGENOL

- The material described must not be used when the application techniques are not possible.
- It is recommended not to apply or remove it completely if light-curing resins are used, since eugenol inhibits polymerization.
- It is not recommended if a strong and long-lasting bond is required.
- Do not use in people allergic to eugenol.
- Do not use in deep cavities near the nerve.

3. Device Description

3.1 Device Description

MEDENTAL Z.O.E. Cements are a family of products made with Zinc oxide powder and Eugenol liquid. Eugenol is the essence of cloves. ZOE cements are generally used as temporary cements with expected duration. (MDR 2017/745. See Annex VIII 1.3 "long term". [Chapter III, Rule 5, point 3]) Of use from one week to four months but also, they can be used as definitive cements.

3.2 Reference to previous generations or variants if they exist, and a description of the differences

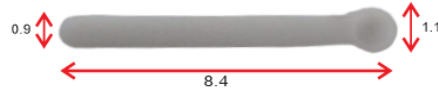
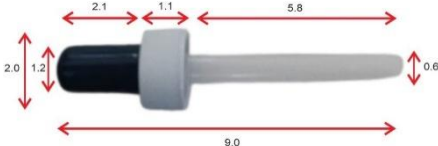
There have been no previous generations of the device produced. The devices currently being produced are of the same design as those produced previously.

3.3 Description of any accessories that are intended to be used in combination with the device

3.3.1 Accessories

According to the MDR, accessories for a medical device are products that are not themselves a medical device and are intended to be used in conjunction with a medical device to enable the device to be used in accordance with the device's intended purpose or to assist the functionality of the device. Temporary Cements with Eugenol Devices Come provided with accessories. The Root Canal Sealer can be purchased in kits of powder and liquid of 20g+10ml. The Z.O.E. Cement Type I can be purchased in kits of powder and liquid of 40g+20ml. The Z.O.E. Cement Type III can be purchased in kits of powder and liquid of 38g+14ml. The Multi-Purpose Z.O.E. Cement can be purchased in kits of powder and liquid of 75g+30ml. The Surgical Dressing Cement can be purchased as a powder of 113g or as a liquid of 56g. The Z.O.E. Cement Type I Fast Setting can be purchased in kits of powder and liquid of 40g+20ml.

Table 1 Accessories

Accessory code	Accessory Name	Image	classification	Description and use with the device(s)
OME00321	Measuring spoon 1		1a	to measure the desired amount to use
OME00545	Dropper		1a	to transfer and measure small, exact amounts of liquid drop-by-drop.
OME00804	Z.O.E. CEMENT TYPE III instructions		1a	DOCUMENT containing instructions on how to use the product

NOTE: The accessories of Temporary Cements with Eugenol are measuring spoons and droppers. The measuring spoons are made of polyethylene plastic. The droppers are made of high density polyethylene and polypropylene.

3.4. Description of other devices and products intended to be used in combination with the device

Temporary Cements with Eugenol It does not require combination with other devices to function as intended.

4. Risks and warnings

4.1 Residual risks and undesirable effects

No adverse interactions have been reported between Temporary Cements with Eugenol and similar products. There are no known side effects of Temporary Cements with Eugenol.

4.2 Warnings and precautions

Actions to be considered in case of harm:

- In case of any change on the original function of the product, stop using it and contact the manufacturer.
- Read carefully and follow all instructions.
- It may cause mild pulp irritation or inflammation immediately after its application.
- It can cause local allergies and contact dermatitis. Its clinical use is relatively safe if handled properly.
- It is recommended to thoroughly clean the remnants before using the final cement or resin.



- Should not be used as a permanent cement.
- Should not be used if a strong bond is required.
- In deep cavities, place a protective intermediate base to avoid irritation.
- Before the use of these products always use rubber dam gloves and protective glasses.
- In case of contact with the eye, wash immediately with plenty of water for at least 15 minutes and if the irritation persists consult a doctor.
- In case of contact with skin wash the area with soap and water.
- The product should not be ingested or aspirated. If accidentally swallowing induces vomiting immediately

4.3 Other relevant safety aspects, including a summary of any field safety corrective measures (FSCA, including FSN), if applicable

There have been no Field Safety Corrective Actions (FSCA) or Field Safety Notices (FSN) for any Conamco SA de CV products.

5. Summary of clinical evaluation and post-marketing clinical follow-up (PMCF)

5.1 Summary of clinical data related to the equivalent device, if applicable

Current clinical data available are based on Conamco SA de CV devices.

5.2 Summary of clinical data from investigations conducted on the device prior to CE marking, if applicable

No specific clinical investigations were performed on the device prior to CE marking.

5.3 Summary of clinical data from other sources, if applicable

has been used, because a device can be used in more than one patient or more than one device can be used in for a single patient, this will depend on the number of molars and teeth to be treated Clinical data is derived from a variety of sources, including use in physicians' offices or clinics and use reported in clinical articles. The clinical data included in the Clinical Evaluation Report uses data collected from actual Conamco SA de CV devices.

Over the years, there have been low-risk problems, ie defects in the primary and/or secondary packaging that do not affect the safety of the device.

We have a history where an adverse event has never occurred, therefore, we do not have CAPAS analysis associated with Temporary Cements with Eugenol devices, which we present below. The total number of users who have used the device has not been measured, nor has the total population of patients in which this device, taking into account the depth of the cavities.

There have been the customer complaints about Water Base Cements in the last 6 years.

During visits to clients, fairs, congresses and distributors the following comments have been made:

- The product is safe.
- Easy to use.
- I have never had any problems with the product.



Compared to total sales over the past 6 years, CONAMCO SA DE CV. has maintained a complaint rate of less than 2% for Water Base Cements. This provides confidence that the products perform safely and effectively in the hands of the intended user. Additionally, this company has received positive feedback from several sources regarding this product.

The literature reviewed in this report did not identify any safety concerns when using the device as intended.

Findings included the following:

ZOE cements contain eugenol, which has a sedative effect. If used in deep cavities, it may cause inflammation.

Some individuals may be sensitive to eugenol and experience local allergic reactions or contact dermatitis; however, its temporary clinical use is generally relatively safe when handled with care. If the temporary cement is not completely removed, it may inhibit resin polymerization or the adhesion of the definitive cement.

ZOE cements possess antibacterial properties.

A protective intermediate base should be used in deep cavities to prevent pulpal irritation.

No adverse reactions compromising patient safety have been demonstrated.

Post-market data confirm that the device is safe for its intended use and performance.

During the period 2021 to 2026, the complaints were received which were not related to the safety of Zinc Oxide Eugenol Cements.

5.4 Clinical performance and safety overview

Device Security

The literature search did not yield any literature specifically related to the Medental Temporary Cements with eugenol. The literature reviewed provides direct clinical evidence of the safety and performance of similar devices having the same composition, design and intended use. During this search, literature relevant to devices considered similar to the Temporary Cements with Eugenol and representing the state of the art for such devices was identified and evaluated. Therefore, information on the safety and performance of those devices, limited to those aspects of similarity to the Temporary Cements with Eugenol, is considered to be directly relevant to the clinical safety and performance of the Medental Temporary Cements with eugenol.

The last investigations on Temporary Cements includes the use of Bio materials like Bioactive sealer as an alternative was because it induces faster healing, or the temporary cements eugenol free. Some articles suggested the use of MTA (Mineral trioxide Aggregate) as etter option, but without the sedative effect of eugenol.

Among the findings were:

- Pulpal irritation in deep cavities close to the nerve
- May cause inflammation immediately after placement, depending on the duration of exposure
- May trigger local allergic reactions and contact dermatitis; clinical use is relatively safe if handled correctly.
- Thorough removal of remnants is recommended to avoid compromising the adhesion of the definitive cement.
- O Over time, the amount of residual eugenol does not increase significantly.



- If resin is to be used, consider a non-eugenol temporary cement and thoroughly remove residues before applying the definitive cement.
- Minimize the time interval between the temporary and definitive restorations to reduce the risk of residual effects.
- In deep cavities, place a protective intermediate base to prevent irritation.

Device performance

Among the key performance data reviewed in the literature, the following findings were noted:

It is an excellent option for use as a temporary cement due to its ease of use and sedative effect.

When light-curing resins are used as the definitive cement, it is preferable to use a non-eugenol temporary cement. If ZOE is used, all residues must be completely removed before placing the definitive cement; failure to do so may inhibit adhesion and polymerization.

ZOE cements can be placed in 3 mm layers.

It is recommended not to delay the definitive restoration beyond the intended duration of use for the temporary cement.

Many ZOE cements have improved their mechanical strength and stability through reinforcement with fibers, additives, or EBA.

Advantages:

- ZOE cement provides a good seal for temporary restorations, helping to protect the dentin/pulp. A powder-to-liquid ratio of 2:1 is recommended.
- Its mechanical properties (low strength) facilitate removal.
- It does not negatively affect bond strength; however, if light-cured resin is used, bond strength is reduced if residues are not thoroughly cleaned away.
- Eugenol has a sedative effect on the pulp (relieving pain) and inhibits bacterial growth.
- Good thermal insulation.
- Cost-effective.

5.5 Ongoing or planned post-marketing clinical surveillance

Clinical evaluations will be conducted to determine any new or previously unidentified risks that could cause a change in the benefit/risk balance. In addition, the evaluations will review any changes to the state-of-the-art.



6. Possible alternative treatments

Alternatives to this treatment.

There are several structural alternatives to preserve teeth.

- Eugenol-Free Zinc Oxide Cements
- Resin-Based Temporary Cements
- Zinc Polycarboxylate Cements

7. Suggested profile and user training.

The Temporary Cements with Eugenol It is intended for use only by licensed dental professionals with academic degree and experience, as well as training in the use of dental materials, (it should be handled only by a dental professional). CONAMCO SA de CV provides instructions for use with indications on how to use the device safely in order for it to achieve its intended purpose.

8. Reference to any harmonized standard and applied CS

Number	Name
EN ISO 10993-1	Biological evaluation of medical devices. Evaluation and testing within a risk management process
EU-MDR/2017/745	Regulation ANNEX XIV, Part A; Annex II, Sections 2, 3 and 4.,
EN ISO 13485	Medical devices. Quality management systems.
EN ISO 14971	Medical devices. Application of risk management to medical devices
EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be provided – Part 1: General requirements
	Clinical evidence required for medical devices previously bearing the CE marking;
MDCG 2020-6	Model clinical evaluation assessment report;
MDCG 2020-13	
MEDDEV 2.7/1	Clinical evaluation: a guide for manufacturers and notified bodies
CGDM 2019-9	Safety and clinical performance summary
MEDDEV 2.12-1	Guidelines on a surveillance system for medical devices

9. HISTORY OF CHANGES

REVIEW TABLE			
Revision	Date	Description of change	Revision validated by the Body Notified
0	09Oct2024	New format	☐ In progress ☐ Yeah Validation language: English ☒ No