



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 EUGENOL FREE:

- Medental Temporary Cement Eugenol Free
- Medental Provisional Cement

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, México

1.3 Manufacturer's Unique Registration Number (SRN)

MX-MF-000020252

1.4 Basic UDI-DI

750229184268726 This basic UDI-DI is only relevant for EU-MDR/2017-745.

1.5 Description/text of medical device nomenclature

Term	Definition
Temporary Cements Eugenol Free	Eugenol Free Cements are recommended when there is an adequate retention, and the preparations have big parallel walls. Most prosthesis can be removed simply by twisting or applying a small force with a crown remover. The provisional Cement is a temporary filling for self-curing. Of use from one week to four months but also, they can be used as definitive cements.
Anterior teeth	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.

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 EUGENOL FREE 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. cement temporary restorations without interfering with the setting (polymerization) of definitive cements or resin-based materials.

2.2 Indication(s) and target population(s)

- a. **Medental Temporary Cement Eugenol Free:** *Is recommended when there is an adequate retention, and the preparations have big parallel walls. Most prosthesis can be removed simply by twisting or applying a small force with a crown remover.*
- b. **Medental Provisional Cement:** *For occlusal temporary seals. For temporary filling after endodontic treatments.*

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 EUGENOL FREE.

2.3 Contraindications

The TEMPORARY CEMENTS EUGENOL FREE

- Do not use if the tooth is very sensitive post-operatively.
- If a sedative effect is sought in a preparation that causes discomfort.
- If it is required that the cement be removed more easily.
- If long-term permanent cementation is required.
- If pulp irritation exists in deep cavities.
- Postoperative discomfort in deep areas.
- Avoid in crowns, bridges, posts and definitive or permanent restorations.
- Avoid use in highly sensitive pediatric patients.
- If there is an allergy to any of the components of the formula.

3. Device Description

3.1 Device Description

MEDENTAL Eugenol Free Cements are recommended when there is an adequate retention, and the preparations have big parallel walls. Most prosthesis can be removed simply by twisting or applying a small force with a crown remover. The provisional Cement is a temporary filling for self-curing. 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. The TEMPORARY CEMENTS EUGENOL FREE Devices is provided with or without accessories.

The accessories of Temporary Cements Eugenol Free are mixing tips to put in a double syringe.

These accessories are compatible with the Temporary Cements Eugenol Free as in shown in the stability tests of each product because the studies show after almost three years, they do not affect the product and the product does not affect them during the shelf life of the products. See the stability studies of each product

See the stability studies.

Table 1 Accessories

Accessory code	Accessory Name	Image	classification	Description and use with the device(s)
OME00321	Mixing tips		1a	to measure the desired amount to use
OME00511	Temporary Cement Eugenol Free Instructions		1a	DOCUMENT containing instructions on how to use the product

NOTE: The accessories for Temporary Cement Eugenol Free are mixing tips. The mixing tips are made of high density polyethylene and silicon.

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

Temporary Cements Eugenol Free 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 Eugenol Free and similar products. There are no known side effects of Temporary Cements Eugenol Free.

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 and get medical attention. In case of inhalation, clean your nose with water and seek medical assistance.
- Ask for patient to rinse his mouth immediately after treatment.
- The product is designed to be used at room temperature.

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, is 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 Eugenol Free 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.

Dental cements can be considered a well-established technology due to their continuous use for more than 30 years, their widespread use in clinical research and investigational protocols, their documented efficacy in short- and long-term studies, their systematic teaching in dental education, and their compliance with international standards. An understanding of well-established chemistry allows for the development of new formulations that focus on making them more efficient or the method of dispensing the product, but the basic principle remains unchanged.

There have been the customer complaints about Temporary Cements Eugenol Free 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 Temporary Cements Eugenol Free. 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.

5.4 Clinical performance and safety overview

Device Security

The literature reviewed in this report did not identify any safety concerns when using the device as intended. Apart from that, the eugenol free cements don't compromise the patient's security, their cytotoxicity is on the cellular level. There are no side effects that have been shown to compromise patient safety.

Among the findings were:

-Non-eugenol formulations were introduced to avoid eugenol's known interference with bonding and polymerization of definitive restorations.

-Se toleran mejor en tejidos pulpares y periodontales.

-No afectan la adhesión ni la polimerización de resinas.

-La ausencia de eugenol reduce la posibilidad de reacciones alérgicas.

-There are no clinical reports of adverse effects caused by non-eugenol temporary cements.

-The evidence of allergic or systemic reactions is not documented.

-Is important to clean perfectly any residue of dental cement to prevent contamination. The residual luting cement around implant restorations is associated with peri-implant mucosal inflammation, is recommendable to manage this observation carefully.

-The development of non-eugenol cements was designed to reduce the risks of eugenol, and there are no documented adverse effects, maybe because clinical data are limited.

The non-eugenol temporary cements have acceptable short-term provisional retention and their effects on final bonding depends on formulation and cleaning.

The biocompatibility on temporary cements eugenol free is favorable in in vitro studies.

Literature searches demonstrate the clinical need for such devices and clearly show that they are state-of-the-art and preferred by many dentists. It was observed that there is now a significant increase in studies on Dental Cements that include the antibacterial function, the self-etch resin cements, fluoride release, stronger adhesive, solubility, retention, setting time or removal facilities in their formulation.

It not found studies that identified a preferred cement, the main finding was that there was no significant difference between cements for key clinical outcomes. It depends on type of restoration and

purpose to use one or another cement. The extensive reference to similar devices in the literature also supports the idea that these devices are state-of-the-art.

Post-market data collected confirms that the device is safe to use for its intended use and performance

During the period 2021 to 2026, the complaints were received which were not related to the safety of Water Base Cements.

Device performance

In Among the most important performance data reviewed in the literature, the following was found: Among the findings were:

Among the most important performance data reviewed in the literature, the following was found:

- Temporary Cements Non-eugenol have limited in long term uses compared with zinc-oxide temporaries.
- The permanent cementation doesn't have to exceed the time estimated to use non- eugenol cement.
- They have lower retention than other cements or resin cements, especially when retrievability is desired.
- Clinically relevant sealing for provisional restorations in short-term simulations.
- Insufficient evidence exists to quantify long-term clinical success.
- Mechanical and chemo-mechanical cleaning protocols of non-eugenol cements can influence restoration bond strength.
- Microleakage in Zinc Oxide Non-eugenol is more in comparison with other cements.
- Adequate mechanical strength.
- Faster setting (less than one minute).
- Reduced solubility.
- More homogeneous texture.
- Easier removal of excess material.
- Moderate short-term compressive strength.

During the period 2021 to 2026, the complaints were received which were not related to the safety of the Medental Temporary Cements Eugenol Free. No complaints related to the performance of the device were reported by Temporary Cements Eugenol Free users and there has been no evidence of any adverse performance issues. The functionality of the device is relatively simple and there are no specific performance-related concerns. Adverse event databases did not reveal any performance issues in similar devices on the market. Their risks are analysed and will be taken into account in risk management, if appropriate.

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.

- Zinc Oxide Cements with Eugenol (ZOE)
- Polycarboxylate Cement
- Zinc Phosphate Cement
- Glass Ionomers Cements

7. Suggested profile and user training.

The Temporary Cements Eugenol Free 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