



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)

WATER BASE CEMENTS

- Medental Zinc Phosphate Cement
- Medental P.C.A. Cement

1.2 Name and address of the manufacturer

Conamco S.A. De C.V. dba Medental

Main Site : Jose Maria Bustillos No. 28 Bis, 1st and 2nd floor. Algarin Colony, Cuauhtémoc
Delegation, CP. Mexico City, 06880, Mexico

1.3 Manufacturer's Unique Registration Number (SRN)

MX-MF-000020252

1.4 Basic UDI-DI

750229184268522 This basic UDI-DI is only relevant for EU-MDR/2017-745.

1.5 Description/text of medical device nomenclature

Term	Definition
Water Base Cements	are intended to be applied for cementation of inlays, crowns, bridges, and orthodontic brackets. Zinc Phosphate Cement: Base Cement for crowns and bridges and P.C.A. Cement: Cementation of Inlays, crowns, bridges, and orthodontic brackets. For base under all types of filling materials. The two cements evaluated are clinically acceptable and can be used in anterior and posterior cementations, each in their respective recommended uses, and are effective
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, 2º - 1º, 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

MEDENTAL Water Base Cements are primarily intended for:

Zinc Phosphate Cement: Base Cement for crowns and bridges.

P.C.A. Cement: Cementation of Inlays, crowns, bridges, and orthodontic brackets. For base under all types of filling materials.

2.2 Indication(s) and target population(s)

Indications:

Zinc Phosphate Cement: Base Cement for crowns and bridges.

Zinc phosphate cement is used for the cementation of restorations made outside the mouth (made in the laboratory) metals such as inlays, crowns, fixed prostheses, it can be used as a base, intermediate and before making the definitive filling.

P.C.A. Cement: Cementation of Inlays, crowns, bridges, and orthodontic brackets. For base under all types of filling materials. A temporary filling for teeth of doubtful prognosis.

Polycarboxylate cement is indicated for the cementation of inlays, onlays, crowns, bridges, orthodontic supports, cement for bases under all types of filling materials, temporary cementation for anterior and posterior teeth.



Population (s)

Water Base Cements can be used in all pediatric or adult patients of any age, gender, weight, or ethnicity, with permanent dentition, who, for different reasons, must be make restorations with Medental Water Base Cements.

2.3 Contraindications

Contraindications for Zinc Phosphate Cement:

- The material described should not be used when the application techniques are not possible.
- It is not recommended for use as a cavity liner because it can irritate the pulp.
- Contraindicated in: Deep cavities or those close to the pulp because it can cause irritation.
- Patients with pulp hypersensitivity or marked sensitivity.
- It is opaque, so it is not recommended when there is a need for high aesthetics.
- Long-term provisional restorations, since it does not release fluoride.
- Cases requiring chemical bonding to the tooth structure.
- Areas subject to extreme stress where its fragility may be a disadvantage.

Contraindications for Polycarboxylate Cement:

- The material described should not be used when the application techniques are not possible.
- It is not indicated for use as a temporary cement because it can be difficult to remove.
- Very large cavities or those with thin walls due to their low strength.
- It is opaque, so it is not recommended for highly aesthetic needs.
- Cases requiring greater fluidity or handling, as its working time is short.
- Patients with a history of allergic reactions to polyacrylic acid
- Areas requiring high mechanical strength.

3. Device Description

3.1 Device Description

- MEDENTAL Water Base Cements are intended to be applied for cementation of inlays, crowns, bridges, and orthodontic brackets. Zinc Phosphate Cement: Base Cement for crowns and bridges and P.C.A. Cement: Cementation of Inlays, crowns, bridges, and orthodontic brackets. For base under all types of filling materials. The two cements evaluated are clinically acceptable and can be used in anterior and posterior cementations, each in their respective recommended uses, and are effective.

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.

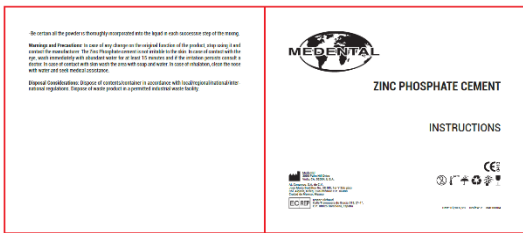
3.3 Description of any accessories that are intended to be used in combination with the device

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. Water Base Cements Devices Come provided with accessories. The Zinc Phosphate Cement can be purchased in kits of powder and liquid of 32g+15ml or 80gr+55ml. and Polycarboxylate Cement device can be purchased in kits of powder and liquid of 25g+15ml or 80g+40ml.

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
OME00804	Phosphate cement instructions		1a	Document containing instructions on how to use the product

NOTE: The accessories of Water Base Cements are measuring spoons, blocks of white paper. The measuring spoons are made of polyethylene plastic. The blocks are made of white polypropylene.

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

Water Base Cements 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 Water Base Cements and similar products. There are no known side effects of Water Base Cements.

4.2 Warnings and precautions

- Read carefully and follow all instructions
- 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.

Precaution



Some patients may present allergies to the components of the formula, in this case, discontinue its use.

- Keep away from Sunlight.
- Keep away from rain.
- Keep away the reach of children.
- Keep away from heat or sparks.
- Temperature limit between 4°C and 24°C. Fragile. Non-Sterile.
- No requires refrigeration Only for professional dental use.
- Room temperature before use.
- Not requires cold chain to transport.
- Do not use after date of expiry.

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

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 WATER BASE CEMENTS 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 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, 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.

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 water base cements can cause a low irritation of the pulp during the application, but doesn'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:

- The acidic pH of Zinc Phosphate Cement can cause inflammation of the pulp tissue at the time of cementation.
- It is important to distinguish the mechanical properties and general characteristics of luting materials in order to identify the best options for each case.
- Zinc Phosphate cement exhibited a moderately harmful effect on mineralization osteoblast cells.
- Non-hardened glass ionomer, resin modified and zinc polycarboxylate cements exhibited moderate antibacterial action.
- The conventional zinc phosphate cement showed the lowest impact on cell viability. On cellular level, highest cytotoxic effects were detected in osteoblastic cell lines.
- Zinc Phosphate Cement showed lower setting temperatures which might not be enough to result in irreversible changes in the pulp tissue, the incidence of pain in patients after restoration placement seems to be typical due to the setting temperature of cements.
- Zinc phosphate cements are easy to manipulate and do not involve acid etching procedures that are operator sensitive into the dentinal tubules.
- Zinc phosphate cement, used successfully for over a century to lute well-fitting metal and metal-ceramic definitive restorations, is a very inexpensive, rigid material which displays very high early compressive strength yet acidity and solubility can be problems. Polycarboxylate cement (a hybrid of zinc phosphate) has lower compressive strength but high tensile strength and may be less injurious to the pulp.
- Zinc Phosphate cements had little inhibitory effect on bacterial acid production. The acidity of ZPC can be neutralized under our experimental conditions, and thus antibacterial activity is probably decreased.
- The addition of copper in low concentrations as given does not have any significant (in vitro and in vivo) effects on microorganisms (or cells) and must therefore be categorized as counterproductive (24)

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:

- It's important to distinguish the physical, mechanical, and biological properties of luting materials in order to identify the best options for each case. Selection of a luting agent can also be based whether it is for short- or long-term use, and certain cements are better for long-term use. There is insufficient high quality evidence with regard to the most effective adhesive for attaching orthodontic bands to molar teeth.
- Both cements have low bond strength and high-water solubility. Polycarboxylate and Zinc phosphate cement are hard to mix and hard to remove.
- Unit bridge no sensitivity during interim good retention Retentive strength of adhesive resin cement and resin modified GIC was significantly greater than that of zinc phosphate.
- It was demonstrated that the core-finishing procedures and time intervals that elapsed after luting did not appear to affect the retention of cast posts-and-cores when zinc phosphate cement was used. The polycarboxylate cements revealed comparable retentive force after days of storage.
- Thermal cycling and ultrasonic instrumentation for 15 min. caused a significant reduction in tensile bond strength ($p < .05$).
- Microleakage in Zinc Polycarboxylate Cement and Zinc Oxide Eugenol cement is similar. (10) The zinc phosphate cement showed higher margin microleakage scores in relation to RMGI and RC cements.
- Zinc polycarboxylate: recommended for use with well-fitting metal and metal ceramic restorations.
- Zinc Phosphate Cement: Its compressive strength is relatively high and tensile strength is low and is very inexpensive per unit dose. It was found that the permanent cements presented higher tensile strength and that the temporary cement could be used in situations that require reversibility and removal of cemented dental implant-supported prostheses.
- For Polycarboxylate Cement there was no relation between cement film thickness and retentive strength.
- The Zinc Oxide powder shows a higher dissolution than Zinc phosphate cements.

During the period 2021 to 2026, the complaints were received which were not related to the safety of the Water Base Cements. No complaints related to the performance of the device were reported by Water Base Cements 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 analyzed 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.



- Resin-Modified Glass Ionomer Cements
- Composite Resins
- Self-Adhesive Resin Cements

7. Suggested profile and user training.

The Water Base Cements 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